Cigna Medical Coverage Policy

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Subject **Cardiac Event Monitors**

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Hyperlink to Related Coverage Policies

Tilt Table Testing

INSTRUCTIONS FOR USE

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Coverage Policy

Continuous 24- to 48-hour External Unattended Cardiac Monitoring Device

Cigna covers the use of a 24- to 48-hour continuous external unattended cardiac monitoring device (e.g., Holter monitor™ [HM]) (Current Procedural Terminology [CPT®] codes 93224, 93225, 93226, 93227) as medically necessary for ANY of the following indications:

- as a diagnostic tool to evaluate symptoms suggestive of cardiac arrhythmias (e.g., frequent palpitations, unexplained dizziness, or syncope)
- assessment of pacemaker or implantable cardioverter defibrillator (ICD) function for **ANY** of the following:
    - frequent symptoms of palpitation, syncope, or near syncope
    - suspected component failure or malfunction
    - assessment of response to drug therapy in an individual with an ICD
- assessment of potential myocardial ischemia in suspected variant angina or known coronary artery disease when such information will impact management
- assessment of antiarrhythmic drug therapy in an individual with a treated arrhythmia
- child with **ANY** of the following:
    - hypertrophic or dilated cardiomyopathy
    - possible long QT syndrome

- congenital heart disease accompanied by a significant residual hemodynamic abnormality when surgery is being considered
- assessment of the adequacy of antiarrhythmic therapy during rapid growth
- asymptomatic non-paced congenital complete atrioventricular (AV) block

Patient or Event Recorder (Loop Recorder)

Cigna covers the use of an external loop recorder (CPT codes 93268, 93270, 93271, 93272) as medically necessary for the identification of a suspected cardiac arrhythmia despite normal findings on ambulatory electrocardiography (AECG).

Cigna covers the use of an implantable loop recorder (CPT codes 33282, 33284, 93285, 93291, 93297, 93298, 93299, C1764, E0616) as medically necessary for the evaluation of recurrent unexplained episodes of fainting when ALL of the following criteria are met:

- cardiac arrhythmia is suspected to be the cause of fainting
- noninvasive ambulatory monitoring failed to establish a definitive diagnosis because the symptoms occur so infrequently and unpredictably that the length of the monitoring period may have been inadequate to capture a diagnostic electrocardiogram (ECG) rhythm disorder
- tilt-table testing is negative or nondiagnostic

External Mobile Outpatient Cardiac Telemetry System

Cigna does not cover an external mobile outpatient cardiac telemetry system (CPT codes 93228, 93229) for any indication because it is considered experimental, investigational or unproven.

Long-term Continuous 48 hour to 21 day External Unattended Cardiac Monitoring Device

Cigna does not cover a 48 hour to 21 day external continuous unattended cardiac monitoring device (CPT codes 0295T—0298T) for any indication because it is considered experimental, investigational or unproven.

Intracardiac Ischemia Monitoring System

Cigna does not cover an intracardiac ischemia monitoring system (CPT codes 0302T—0307T) for any indication because it is considered experimental, investigational or unproven.

Other Cardiac Event Monitors

Cigna does not cover ANY of the following for any indication because each is considered a convenience item and not medically necessary:

- a self-monitoring combination device that includes an ECG monitor combined with a cellular telephone or other personal electronic device
- additional software or hardware required for downloading ECG data to a device such as personal computer, smart phone, or tablet

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General Background

Cardiac arrhythmias or abnormal heartbeats represent a major source of morbidity and mortality among patients with cardiovascular disease. While some patients with arrhythmias may experience palpitations, weakness, dizziness, or syncope, other patients may have no symptoms at all. Some arrhythmias pose a significant health threat and require prompt treatment. Treatments for arrhythmias include medical therapy, artificial pacemakers, implanted cardiac defibrillators, and ablation of malfunctioning cardiac tissue. Effective treatment of arrhythmias requires an early diagnosis. This can be difficult, since arrhythmias can occur infrequently and unpredictably and

may be asymptomatic. Therefore, devices that monitor a patient's heartbeat for an extended period of time and can automatically detect certain arrhythmias are desirable (ECRI, 2010).

Remote cardiac monitoring technologies allow home ECG monitoring of patients with suspected cardiac arrhythmias or at risk for developing arrhythmias. This is also referred to as ambulatory electrocardiography (AECG). Because certain abnormalities may occur only during sleep or with mental, emotional, or exercise-induced changes in cardiac oxygenation or function, an ECG may need to be recorded over long periods of time. AECG has proven to be useful for the diagnosis and management of patients at high risk for life-threatening cardiac arrhythmias (Agency for Healthcare Research and Quality [AHRQ], 2007; Hammill, 2007; Kadish, et al., 2001).

The categories of remote cardiac monitoring technologies include (AHRQ, 2007; Mittal, et al., 2011; U.S. Food and Drug Administration (FDA), 2012):

- continuous 24- to 48-hour external unattended cardiac monitoring device (e.g., Holter monitoring™ [HM])
- long-term continuous 48- to 21-day external unattended cardiac monitoring device
- patient- or event-activated device
    - externally-worn presymptom memory loop recorder (attended and unattended)
    - implantable/insertable presymptom memory loop recorder (attended and unattended)
    - post-symptom patient activated recorder
- real-time continuous attended cardiac monitoring system

Continuous 24- to 48-hour External Unattended Cardiac Monitoring Device: The most common device used is called a Holter monitor™ (HM). The recording device of an HM is worn on a strap at the waist or over the shoulder. The electrical signals of the heart are picked up by two electrodes attached to the chest, and these are connected to the recorder by wires. HM generally provides a continuous 24- to 48-hour record of the electrical signals from the heart. While wearing the HM, the individual keeps a diary of all activities and symptoms. The data is computer analyzed and interpreted by a physician at a later time (Olgin, 2011; Noble, et al., 2004).

The American College of Cardiology/American Heart Association (ACC/AHA) practice guidelines for ambulatory electrocardiography (AECG) state there are two categories of AECG recorders: continuous and intermittent recorders. The authors assigned their highest level (i.e., Class I) of evidence to the following indications for AECG (Crawford, et al., 1999). There have been no updates to these guidelines since 1999:

- to assess symptoms possibly related to rhythm disturbances
    - patients with unexplained syncope, near syncope, or episodic dizziness in whom the cause is not obvious; patients with unexplained recurrent palpitations
- to assess antiarrhythmic therapy:
    - to assess antiarrhythmic drug response in individuals in whom baseline frequency of arrhythmia has been characterized as reproducible and sufficient to permit analysis
- to assess pacemaker and implantable cardioverter defibrillator (ICD) function:
    - evaluation of frequent symptoms of palpitation, syncope, or near syncope to assess device function to exclude myopotential inhibition and pacemaker-meditated tachycardia, and to assist in the programming of enhanced features such as rate responsivity and automatic switching
    - evaluation of suspected component failure or malfunction when device interrogation is not definitive in establishing a diagnosis
    - to asses the response to adjunctive pharmacological therapy in patients receiving frequent ICD therapy

- for ischemic monitoring:
    - patients with suspected variant angina
- for pediatric patients:
    - syncope, near syncope, or dizziness in patients with recognized cardiac disease, previously documented arrhythmia, or pacemaker dependency
    - syncope or near syncope associated with exertion when the cause is not established by other methods
    - evaluation of patients with hypertrophic or dilated cardiomyopathies
    - evaluation of possible or documented long QT syndromes
    - palpitation in the patient with prior surgery for congenital heart disease and significant residual hemodynamic abnormalities
    - evaluation of antiarrhythmic drug efficacy during rapid somatic growth
    - asymptomatic congenital complete atrioventricular (AV) block, nonpaced

Patient or Event Recorder (Loop Recorder): The patient or event recorders can be used for a longer time (e.g., 30 days) than a HM and is more likely to record infrequent abnormal heart rhythms. The information collected by a patient or event recorder can be sent over the phone to a doctor's office, clinic, or hospital. The advantage of event recorders over the continuous ambulatory systems is that the ECG is more likely to be obtained while the patient is experiencing clinical symptoms, therefore allowing a direct correlation between the patient's symptoms and the ECG recorded at that instant (Miller, et al., 2011; AHRQ, 2007; Hammill, 2007; Noble, et al., 2004). Examples of patient or event recorders include:

- Externally-worn presymptom memory loop recorders (attended and unattended): This is a small device that attaches to the chest with electrodes. The standard external loop recorder records several minutes of activity at a time and then starts over, a process referred to as memory loop recording. The patient activates this device to record when a symptom occurs and then data from the device is typically transmitted to a monitoring center for immediate review. This process is repeated whenever symptoms occur over a period of 20–30 days (which is the typical amount of time the device is worn by the patient). Since the data that are recorded by the device are typically associated with a symptom, a physician can also determine whether that symptom is a result of a cardiac arrhythmia. However, due to the need for the patient to signal an event, the standard cardiac event monitor typically only captures events associated with a patient's symptoms and not those events that are asymptomatic.

  The auto-trigger external loop recorder also memory loop records, capturing several minutes of heart activity at a time before starting over. In addition, the auto-trigger external loop recorder uses systems to automatically detect events that may not be associated with a patient experiencing symptoms. Unlike a standard external loop recorder, an auto-trigger external loop recorder does not rely on the patient's ability to activate it and, as a result, is able to capture asymptomatic events in addition to symptomatic ones. However, the auto-trigger device still relies on the patient to call in and transmit the event by reaching the physician or a technician at a physician's office or a monitoring center and holding the cardiac event monitor up to a telephone to transmit the event data.

- Implantable/insertable presymptom memory loop recorders (attended and unattended).
  An implantable or insertable memory loop recorder (ILR) is inserted under the patient's skin at about the second rib on the left front of the chest and is activated by passing a special magnet over the device. The main difference between the ILR and the external loop recorders is that the ILR can be used for a much longer time period. Current models are capable of recording from 14–20 months before being surgically removed. It is capable of recording up to 42 minutes of a single ECG channel that can be partitioned for one to seven episodes, with up to 20 minutes of preactivation ECG saved for subsequent downloading to a programming unit for analysis. The device can be configured to store patient-activated, automatically activated recordings (e.g., heart rate outside

preset parameters), or a combination of these. The ILR is used when syncope is infrequently detected by either an HM or a 30-day event recorder.

- Post-symptom patient-activated recorders: This handheld device is used only when symptoms occur. It does not have electrodes that are attached to the chest. When symptoms occur, the patient presses a button to start the ECG recording. The back of the device has small metal discs that function as the electrodes. The post-event monitor typically stores the data for up to 30 days which is transmitted telephonically or through a computer to a receiving center or doctor's office after the event.

U.S. Food and Drug Administration (FDA)
Continuous External Unattended Cardiac Monitoring Devices (HM) and Patient or Event Recorder (Loop Recorder): There are numerous manufacturers of continuous external unattended cardiac monitoring devices and patient or event recorders which can be found on the FDA Center for Devices and Radiologic Health 510(k) database (FDA, 2010). Examples of implantable memory loop recorders include the Reveal® Insertable Loop Recorder (Medtronic, Inc., Minneapolis, MN) which received 510(k) premarket approval from the FDA in February 2001 as a Class II device (FDA, 2001).

Literature Review
Continuous 24- to 48-hour External Unattended Cardiac Monitoring Device/Patient or Event Recorder (Loop Recorder): The peer-reviewed medical literature supports the clinical utility of standard cardiac event monitors such as the HM and loop recorders. Evidence in the published literature consists of systematic reviews, case studies and few well-designed clinical trials (Hindricks, et al., 2010; Giada, et al., 2007; Brignole, et al., 2006; Reiffel, et al., 2005; Farwell, et al., 2004; Sivakumaran, et al., 2003; Krahn, et al., 2001; Krahn, et al., 1999).

Long-term Continuous 48 hour to 21 day External Unattended Cardiac Monitoring Device: Long-term continuous external unattended cardiac monitoring devices provide continuous recording of the electrical activity of the heart for more than 48 hours and up to 21 days. These devices are suggested to increase detection of arrhythmias. A physician analyzes the recording to identify heart rhythm abnormalities. An example of these devices is the Zio®Patch (iRhythm Technologies, Inc., San Francisco, CA), which can record up to 14 days of activity (Mittal, et al., 2011).

U.S. Food and Drug Administration (FDA)
Long-term Continuous External Unattended Cardiac Monitoring Device: The FDA indications for use for the Zio® Patch (iRhythm Technologies, Inc., San Francisco, CA) states it is a prescription only single patient use, continuous recording EGG monitor that can be worn for up to 14 days. It is indicated for use on patients who experience transient symptoms such as syncope, palpitations, shortness of breath, or chest pains (FDA, 2012).

Literature Review
Long-term Continuous External Unattended Cardiac Monitoring Device: There is a lack of evidence in the published peer-reviewed medical literature supporting the clinical utility of long-term continuous external unattended cardiac monitoring devices. Studies are required to evaluate how long-term continuous external unattended cardiac monitoring devices can change treatment management and improve health outcomes compared to standard cardiac event monitors (Rosenberg, et al., 2012).

External Mobile Outpatient Cardiac Telemetry System: The external mobile outpatient cardiac telemetry continuous attended monitoring systems have been promoted for use as alarm systems for long-term monitoring in patients. When using this technology, the patient wears a portable electrocardiogram sensor with leads attached to the patient's skin for continuous monitoring of cardiac rhythms during daily activities. If the algorithm of the monitoring system detects an arrhythmic event, the system will automatically transmit the ECG data wirelessly or through a phone line to a service center. Here, experienced monitoring specialists analyze the data, respond to events, and report results in the manner prescribed by the physician. The patient can also manually send the ECG data by pressing a button when experiencing a symptom. Physicians can monitor a patient's cardiac rhythm for weeks (ECRI, 2010).

U.S. Food and Drug Administration (FDA)

External Mobile Outpatient Cardiac Telemetry System: CardioNet Mobile Cardiac Outpatient Telemetry™ (MCOT™) Services uses the CardioNet (Philadelphia, PA) home-based, real-time cardiac surveillance system. The CardioNet ambulatory ECG monitor received initial 510(k) premarket approval from the FDA in May 2001. The 2001 FDA intended use states, "The CardioNet Ambulatory ECG Monitor is a 3 channel ambulatory ECG monitor capable of recording and transmitting up to 24 hours of ECG data for the purpose of cardiac monitoring and diagnosis by a medical professional. The system includes recording and trans-telephonic transmitting circuitry, a graphic LCD and firmware. The system records ECG and transmits the ECG data to a remote central receiving station. The quality of the ECG data is suitable for analysis by another device to identify cardiac rhythm disorders, heart rate variability, reporting of QT interval and ST changes. The device is not intended to sound any alarms".

The CardioNet ECG Monitor with Arrhythmia Detection received 510(k) premarket approval from the FDA in February 2002. The CardioNet ECG Monitor with Arrhythmia Detection is referred to as the subject device and is a modification to the CardioNet Ambulatory ECG Monitor. The subject device includes the addition of an ECG analysis capability that allows detection of cardiac arrhythmia. The indications for use for the subject device is as follows:

- Patients who have demonstrated a need for cardiac monitoring and are at low risk of developing primary ventricular fibrillation or sustained ventricular tachycardia.
- Patients with dizziness or lightheadedness
- Patients with palpitations
- Patients with syncope of unknown etiology
- Patients who require monitoring for life-threatening arrhythmias, such as atrial fibrillation, other supra-ventricular arrhythmias, evaluation of bradyarrhythmias and intermittent bundle branch block. This includes post operative monitoring of these arrhythmias.
- Patients recovering from CABG surgery who require monitoring for arrhythmias.
- Patients requiring monitoring for arrhythmias induced co-morbid conditions such as hyperthyroidism or chronic lung disease.
- Patients with obstructive sleep apnea to evaluate possible nocturnal arrhythmias.
- Patients requiring arrhythmia evaluation for etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation.
- Data from the device may be used by another device to analyze, measure or report QT interval. The device is not intended to sound any alarms for QT changes.

Another real-time system is the HEARTLink™ II, manufactured by Cardiac Telecom Corporation (Greensburg, PA) which uses Telemetry@ Home (FDA, 1998). Other examples of real-time systems include the CG-6108 Arrhythmia ECG Event Recorder (Card Guard Scientific Survival Ltd, Rehovot, Israel) which is also known as the Lifestar Ambulatory Cardiac Telemetry (ACT) by Life Watch Services, Inc. (Rosemont, IL), the Vital Signs Transmitter (VST)™ (Biowatch Medical, Inc., Columbia, SC), NUVANT™ Mobile Cardiac Telemetry (MCT) System (Corventis™, San Jose, CA) (FDA, 2009; FDA, 2006; FDA, 2004).

Literature Review

External Mobile Outpatient Cardiac Telemetry System: There is limited evidence in the published peer-reviewed medical literature supporting the clinical utility of external mobile outpatient cardiac telemetry systems. Many of the studies lack a comparator and do not report long-term outcomes. Additional studies with long-term follow-up are required to evaluate how real-time surveillance systems can change treatment management and improve health outcomes compared to standard cardiac event monitors.

Cryptogenic Stroke

Miller et al. (2012) conducted a retrospective analysis to verify the previously reported high rate of atrial fibrillation detection over 21 days of MCOT monitoring, assess optimal monitoring duration, and define the factors predicting detection of paroxysmal atrial fibrillation (PAF) in patients with cryptogenic cerebral ischemia. A total of 156 patients were evaluated by mobile cardiac outpatient telemetry (MCOT) monitoring utilizing the CardioNet MCOT system within six months of a cryptogenic stroke or transient ischemic attack with an unidentified cause. PAF occurred in 27 of 156 (17.3%) patients during MCOT monitoring of up to 30 days. The rate of PAF detection significantly increased from 3.9% in the initial 48 h, to 9.2% at 7 days, 15.1% at 14 days, and 19.5% by 21 days ($p<0.05$). Female gender, premature atrial complex on ECG, increased left atrial

diameter, reduced left ventricular ejection fraction and greater stroke severity were independent predictors of PAF detection on multivariate analysis with strongest correlation seen for premature atrial complex on ECG (p=0.001).No adverse events were reported. This study is limited by design lacking a control or comparator group.

Kamel et al. (2012) conducted a pilot study randomly assigning 40 patients with cryptogenic ischemic stroke or high-risk transient ischemic attack to wear a CardioNet mobile cardiac outpatient telemetry monitor for 21 days or to receive routine follow-up alone. Patients with documented atrial fibrillation (AF) or other apparent stroke pathogenesis were excluded. Patients and their physicians were contacted at three months and at one year to ascertain any diagnoses of AF or recurrent stroke or transient ischemic attack. In the monitoring group, patients wore monitors for 64% of the assigned days and 25% of patients were not compliant at all with monitoring. No patient in either study arm received a diagnosis of AF. Cardiac monitoring revealed AF in zero patients, brief episodes of atrial tachycardia in two patients, and nonsustained ventricular tachycardia in two patients. No adverse events were reported. This study was limited by small sample size. The authors reported that given the remaining uncertainties in this field and the different monitoring strategies available, results from ongoing trials will be needed to identify optimal strategies for diagnosing AF as a cause of cerebral ischemia, thereby reducing the incidence of recurrent stroke.

In a cohort study, Bhatt et al. 2011 sought to determine the percentage of patients with cryptogenic stroke who had paroxysmal atrial fibrillation (PAF) on prolonged non-invasive cardiac monitoring using the CardioNet MCOT system. The study included a total of 62 patients with stroke (n=50) and TIA (n=12) who underwent prolonged non-invasive cardiac monitoring up to 28 days after discharge. PAF was detected in 15 (24%) of the patients with 97% of the PAF episodes were silent or absent of symptoms suggestive of an arrhythmia. The majority, 14 (93%), of the PAF were detected within the first 21 days. It was not reported whether detecting PAF in the patients warranted change in therapy. This study was limited by small sample size. The authors reported that the role of implantable devices to detect PAF may facilitate longer duration of monitoring, which needs to be investigated.

In a case series study, Tayal et al. (2008) analyzed 56 patients with cryptogenic transient ischemic attack (TIA) or stroke after diagnostic evaluation and Mobile MCOT for up to 21 days. Demographic, radiographic, echocardiographic, and MCOT results were reviewed. The inclusion criteria were: age greater than 18 years; ischemic stroke or TIA within the last three months; and diagnosis of cryptogenic TIA/stroke. TIA was defined as sudden-onset focal neurologic symptoms or signs that resolved within 24 hours and was not associated with high-intensity abnormality in the diffusion-weighted sequence. TIA symptoms and signs included hemiplegia/hemiparesis, monoplegia/monoparesis, aphasia, transient monocular blindness, vertigo, dysarthria, and isolated sensory symptoms. The exclusionary criteria included: history of AF; admission ECG, inpatient cardiac telemetry monitoring, or 24-hour Holter data that demonstrated AF prior to initiation of MCOT; and prothrombotic state. The median MCOT monitoring duration was 21 (range 5–21) days resulting in an AF detection rate of 23% (13/56). AF was first detected after a median of 7 (range 2–19) days of monitoring. Twenty-seven asymptomatic AF episodes were detected in the 13 patients, of which 85% (23/27) were <30 seconds and the remaining 15% (4/27) were 4–24 hours in duration. Prior to the initiation of MCOT, 82.1% (46/56) of the patients were receiving antiplatelet medication, 14.3% (8/56) were receiving warfarin, and 3.6% (2/56) were receiving both antiplatelet medication and warfarin. MCOT results altered patient management in the 13 patients found to have new onset AF by MCOT. Five patients had their antiplatelet medication changed to warfarin, six patients were maintained on the warfarin they were taking prior to MCOT, and two patients were maintained on antiplatelet medication. A reported limitation of this study was the absence of an age-matched control group without a history of TIA/stroke. In addition, not all patients underwent a transesophageal echocardiography (TEE) in this cohort. Another limitation of this study was lack of reported long-term follow-up to determine whether altered patient management improved health outcomes.

Other Indications:
Kadish et al. (2010) retrospectively analyzed patient characteristics, diagnostic yield, and diagnoses of patients in a large commercial database (LifeWatch Services, Inc., Rosemont, Illinois). The purpose of the present study was to evaluate the potential advantage of the immediate response feature. All patients (n=26,438) who underwent monitoring from April to December 2008 at a single service provider formed the patient population of this study. Arrhythmic events noted in these patients were defined as those requiring physician notification and those that represented potentially life-threatening arrhythmias. Of the 26,438 patients included in the study, 5459 (21%) had arrhythmic events meeting physician notification criteria during a mean monitoring period of 21

days. Of these, 262 patients (1%) had arrhythmic events that could potentially be classified as emergent. These included 120 patients with wide complex tachycardia >15 beats at >120 beats/min, 100 patients with pauses >6 seconds, and 42 patients with sustained heart rates <30 beats/min. An additional 704 patients (3%) had narrow complex tachycardia >180 beats/min at rest. Limitations of the study include lack of a comparison group, no information on patient outcomes and detailed information on the patient population was not reported.

In a retrospective study, Saarel et al. (2008) reported on the use of the MCOT system for evaluation of children and adolescents with suspected cardiac arrhythmia. Patients older than 21 years and those with previously documented arrhythmia were excluded. A total of 59 MCOT studies were performed. Five patients met exclusion criteria leaving 54 subjects (mean age 12.4+/-4.5 years; range 3.2–19.7 years; 46% male) for inclusion. Half of the subjects had been previously monitored with a Holter (n=24), transtelephonic electrocardiographic event monitors (n=1), or both (n=2). Among these subjects, the diagnostic yield for MCOT was similar to the overall study population (59%, n=16/27). Twenty-one subjects (39%) did not experience symptoms during MCOT, yielding a diagnostic rate of 61% (n = 33). Of the 33 diagnostic studies, 9% (n=3; mean age 16.9+/-0.6 years; range 16.2–17.3 years; one male) showed supraventricular tachycardia and 9% (n=3; mean age 11.1+/-2.7 years; range 8.2–13.5 years; one male) showed supraventricular or ventricular ectopy. Minor skin irritation at sites of electrode placement was the only complication of MCOT (n=5). The reported limitations of this study include small sample size, retrospective data analysis, and nonrandomized design. Another limitation of this study was lack of follow-up to determine whether patient outcomes were improved as a result of diagnostic information provided by MCOT.

Rothman et al. (2007) conducted a multicenter, randomized, nonblinded controlled trial evaluating the CardioNet system versus a patient-activated external loop event monitor for symptoms thought to be due to a cardiac arrhythmia. The study included 305 patients at 17 centers. The inclusion criteria were: a high clinical suspicion of a malignant arrhythmia; symptoms of syncope, presyncope, or severe palpitations occurring less frequently than once per 24 hours (presyncope was defined as transient dizziness, lightheadedness, unsteadiness, or weak spells without loss of consciousness; severe palpitations were defined as palpitations that would warrant referral for cardiac monitoring); and a nondiagnostic 24-hour Holter or telemetry monitor within 45 days prior to enrollment. Exclusion criteria were New York Heart Association (NYHA) Class IV heart failure, myocardial infarction within the prior three months, unstable angina, candidate for or recent valvular cardiac surgery, history of sustained ventricular tachycardia or ventricular fibrillation, complex ectopy defined as ventricular premature depolarizations ≥ 10/hour with a documented ejection fraction ≤ 35%, patients < 18 years of age, and a concomitant condition prohibiting completion of or compliance with the protocol. The primary endpoint was the confirmation or exclusion of a probable arrhythmic cause of the patient's symptoms (e.g., syncope, presyncope, or palpitations). Arrhythmias were classified as either clinically significant or clinically insignificant, and then the investigators evaluated the temporal relationship of any symptoms and the likelihood that a clinically significant arrhythmia caused the patient's presenting symptoms.

The patients were randomized to 30 days of monitoring with MCOT (MCOT Group n=134) or with an external patient activated loop monitor (Loop Group n=132). Out of the 305 randomized patients, 266 patients completed a minimum of 25 days of monitoring. The most common reason for not completing the protocol was patient noncompliance (13 MCOT patients and seven LOOP patients). Seven patients found the devices too difficult or cumbersome to use; seven patients had an allergic reactions or skin irritation to the electrodes; and six patients stated the monitors interfered with their work or travel. Most of the patients in the Loop Group were required to activate the recorder when they experienced symptoms; however, 49 (18%) patients were at centers that had autotriggered recording of cardiac events. During monitoring, clinically significant arrhythmias were detected in 55 (41%) patients in the MCOT Group versus 19 (14%) patients in the Loop Group, a statistically significant difference ($p<0.001$). For patients who had syncope or presyncope, clinically significant arrhythmias were detected in 52% of patients with MCOT and in 15% of patients with loop recorders. In most cases, the arrhythmias detected were AF, atrial flutter, or ventricular tachycardia. A subgroup analysis was performed at the institutions that used autotriggered loop monitoring rather than patient-activated monitoring. A definitive diagnosis was obtained in this subgroup for 88% of MCOT Group patients versus 46% of Loop Group patients ($p<0.0025$).However, this subgroup analysis involved a relatively small number of patients, and the autotriggered devices may have had single ECG leads, whereas the CardioNet system uses double ECG leads. The authors state the proportion of patients reporting symptoms was similar in both groups (79% in MCOT and 76% in LOOP), suggesting equal compliance during the early portion of the monitoring period when most transmissions and reported symptoms occurred. This study did not address the impact of the real-time

monitoring features on the long-term health outcomes compared to the loop monitor. This study did not discuss how patient treatment changed as a result of the diagnostic information obtained from the CardioNet system.

In a case series study, Olson et al. (2007) evaluated the records of 122 consecutive patients using MCOT for palpitations (n=76), presyncope/syncope (n=17), or to monitor the efficacy of a specific antiarrhythmic therapy (n=29). Ten of 17 patients (59%) studied for resyncope/syncope had a diagnosis made with MCOT. Eight of these 17 patients had a previous negative evaluation for presyncope/syncope (e.g., holter or event monitor) and five had an event correlated with the heart rhythm during the monitoring period. Nineteen patients monitored for palpitations or presyncope/syncope were asymptomatic during monitoring but had a prespecified arrhythmia detected. When MCOT was used as the first ambulatory monitoring system to evaluate palpitations (n=18), 73% of patients correlated their symptoms with the underlying cardiac rhythm. Seven of 21 patients monitored for medication titration had dosage adjustments during outpatient monitoring. Eight patients underwent MCOT monitoring following radiofrequency ablation for atrial fibrillation (AF) (n=5), atrial flutter (n=1), premature ventricular complexes (n=1), and inappropriate sinus tachycardia (n=1). Two patients experienced symptoms during MCOT monitoring. One patient experienced symptomatic premature atrial complexes and the other had sinus rhythm during their symptomatic episode. There was one occurrence of asymptomatic AF in a patient following radiofrequency ablation of AF. A limitation of this study is the uncontrolled study design. There is no comparison to other ambulatory monitoring systems. No long-term health outcomes were reported.

In a small uncontrolled study, Vasamreddy et al. (2006) used the CardioNet monitoring system to assess the efficacy of cardiac tissue ablation procedures for treatment of atrial fibrillation. This is the first study reporting the outcomes of mobile cardiac telemetry monitoring following catheter ablation of AF. A total of 19 patients with highly symptomatic drug refractory AF underwent catheter ablation. Each was provided with an MCOT monitor and was asked to wear it five days immediately before the ablation, and five days per month starting with the ablation for six consecutive months. When patients experienced any symptoms, they were asked to activate the system and to record associated symptoms. Out of the total 390 events triggered by patient's symptoms, 40% were confirmed as AF events (156) and 60% were confirmed as non-AF events (234). Only shortness of breath and chest discomfort were highly associated with AF ($p< 0.05$). At the end of six months of follow-up, out of 10 patients who completed the study, seven (70%) patients were free of symptomatic AF recurrences, whereas only five (50%) patients achieved success when asymptomatic AF recurrences were included in the outcome. Poor patient compliance with a very intensive monitoring protocol was reported as an important limitation of using the CardioNet monitoring system. Only 53% of the study participants were able to complete the study protocol. A limitation of this study was the lack of a comparator and lack of long-term follow-up to determine whether patient outcomes were improved as a result of diagnostic information provided by CardioNet.

In a case series study, Joshi et al. (2005) reported data from the first 100 consecutive patients monitored by an MCOT system who were undergoing treatment for known arrhythmias or who were suspected to have arrhythmias based on symptoms such as palpitations, dizziness, or syncope. The effectiveness of MCOT was assessed based on detection of arrhythmias and changes in patient management after MCOT. A clinically significant arrhythmia was detected in 51 patients, but 25 (49%) did not have any symptoms during the arrhythmia. Thirteen of the 17 patients (76%) found to have atrial flutter/fibrillation had no symptoms during the arrhythmia. Thirty patients had been previously monitored by either an HM or an event recorder. MCOT detected an arrhythmia in 16 of the patients that was not found by a previous monitoring system. One patient had sustained ventricular tachycardia who required an implantable cardioverter-defibrillator. Following MCOT, physicians prescribed the following changes in treatment on a perpatient basis: drug treatment started (n=14), permanent pacemaker inserted (n=5), cardiac tissue ablated (n=4), drug treatment changed (n=3), cardioverter defibrillator implanted (n=2), anticoagulation stopped (n=2), pacemaker replaced (n=1), and drug treatment stopped (n=1). A limitation of this study was the lack of a comparator and long-term follow-up to determine whether patient outcomes were improved as a result of diagnostic information provided by MCOT.

Systematic Review

The Centers for Medicare & Medicaid Services (CMS) requested that the AHRQ commission an evidence report to evaluate remote cardiac monitoring devices. The AHRQ contracted the Evidence-based Practice Center (ECRI) to prepare an evidence report on this topic. The systematic review focused on two major categories of remote cardiac monitoring devices. The first category included patient- or event-activated devices, which include externally-worn presymptom memory loop recorders (attended and unattended), implantable/insertable presymptom memory loop recorders (attended and unattended), and post-symptom patient-activated recorders. The second category comprises real-time continuous attended cardiac monitoring systems. Continuous

unattended cardiac monitoring (e.g., Holter monitoring), prehospital (in ambulance) monitoring and transmission, as well as monitoring solely for the purpose of detecting device failure, was beyond the scope of this report. The systematic review focused on the downstream utility of a diagnostic technology. The overall conclusions state that "Patients with unexplained syncope are more likely to undergo a change in disease management when using ILR monitoring or real-time continuous attended monitoring than used with conventional assessment (i.e., Holter monitoring and/or tilt table testing). Patients with severe palpitations occurring less than once per 24 hours are also more likely to undergo a change in disease management when using real-time continuous attended monitoring. The strength of evidence is moderate for ILR and weak for real-time continuous monitoring (based on one high-quality multicenter trial). Due to small numbers of studies identified and numerous quality flaws, the evidence was insufficient to evaluate the effect of other remote monitoring devices (ELRs and post-event recorders) on change in disease management. For the same reasons, the evidence is also insufficient to determine any class of remote cardiac monitoring devices leads to better clinical outcomes than conventional monitoring" (AHRQ, 2007).

Intracardiac Ischemia Monitoring System: The AngelMed Guardian® system (Angel Medical Systems, Shrewsbury, NJ) is an implantable cardiac device similar to a pacemaker but it monitors the heart's electrical signals 24 hours a day, seven days a week. It is suggested that this device can detect rapid ST segment changes that may signify major cardiac events such as coronary artery occlusions. When an event occurs the system is designed to alert patients to seek medical care by delivering a series of vibratory, auditory, and visual warnings. At the hospital the doctor can retrieve information collected by the implanted device to a computer to help determine a plan of treatment. The system, currently commercially available in Brazil, is the subject of a phase-II clinical study in the United States and has not received PMA or 501(k) FDA-approval at this time.

Literature Review

Intracardiac Ischemia Monitoring System: There is a lack of evidence in the published peer-reviewed medical literature supporting the clinical utility of an intracardiac ischemia monitoring system for any indication (Fischell, et al., 2010).

Other Cardiac Event Monitors: Some cardiac event monitors combine a cellular phone with a heart monitor. This type of self-monitoring device can be used without a physician's prescription. One example is the AliveCor Heart Monitor (AliveCor, Inc., San Francisco, CA). This is an iPhone-enabled heart monitor that has been known as the iPhoneECG. It is in a thin case with two electrodes that snap onto the back of an iPhone. To obtain an ECG recording, the individual holds the device while pressing fingers from each hand onto the electrodes. It has been proposed that the device can obtain an ECG from the patient's chest. The AliveCor ECG iPhone application can record rhythm strips of any duration to be stored on the phone and uploaded securely for later analysis, sharing, or printing through AliveCor's website. The AliveCor Heart Monitor operates for about 100 hours on a 3.0 V coin cell battery. These self-monitoring devices and/or software applications that are used for downloading ECG data to a device such as personal computer, smart phone, or tablet are considered convenience items for the individual and not medically necessary for any indication.

U.S. Food and Drug Administration (FDA)

Other Cardiac Event Monitors: The Alivecor heart monitor for iphone received 510(k) premarket approval from the FDA in November 2012. FDA indications for use state, "The AliveCor Heart Monitor for iPhone is intended for use by licensed medical professionals or patients to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms" (FDA, 2012).

Professional Societies/Organizations

American College of Cardiology (ACC)/American Heart Association (AHA)/European Society of Cardiology (ESC)/Heart Rhythm Society (HRS)

The American Heart Association (AHA)/American College of Cardiology (ACC)/Heart Rhythm Society (HRS) focused update to the 2006 practice guideline on the management of patients with atrial fibrillation states that "The diagnosis of AF requires ECG documentation by at least a single-lead recording during the arrhythmia, which may be facilitated by review of emergency department records, Holter monitoring, or transtelephonic or telemetric recordings." The authors state that "prolonged or frequent monitoring may be necessary to reveal episodes of asymptomatic AF, which may be a cause of cryptogenic stroke. Ambulatory ECG (e.g., Holter) monitoring is also useful to judge the adequacy of rate control. This technology may provide valuable information to guide drug dosage for rate control or rhythm management" (Fuster, et al., 2011).

The AHA/ACC scientific statement on the evaluation of syncope states: “The type and duration of ambulatory ECG monitoring is dictated by the frequency of symptoms. A Holter monitor is appropriate for episodes that occur at least every day. Event monitoring is ideal for episodes that occur at least once a month. An implantable loop monitor allows the correlation of symptoms with the cardiac rhythm in patients in whom the symptoms are infrequent. In patients with unexplained syncope, use of an implantable loop recorder for one year yielded diagnostic information in more than 90% of patients. This approach is more likely to identify the mechanism of syncope than is a conventional approach that uses Holter or event monitors and electrophysiological testing” (Strickberger, et al., 2006). There have been no updates to this statement since 2006.

The AHA/ACC/ European Society of Cardiology Committee (ESC) guideline on the management of patients with ventricular arrhythmias and prevention of sudden cardiac death assigns Class levels and levels of evidence to their recommendations for ambulatory electrocardiography (AECG) (Zipes, et al., 2006). There have been no updates to this guideline since 2006. This guideline does not mention external mobile outpatient cardiac telemetry systems.

Guideline recommendations are classified as Class I, Class IIa, Class IIb, and Class III. The classification system is described as follows:

- Class I: Benefit >>>Risk; Procedure/Treatment should be perfomed/administered
- Class IIa: Benefit >> Risk; Additional studies with focused objectives needed. It is reasonable to perform procedure/administer treatment
- Class IIb: Benefit ≥ Risk; Additional studies with broad objectives needed; additional registry data would be helpful. Procedure/treatment may be considered.
- Class III: Risk ≥ Benefit; Procedure/treatment should not be performed/administered, since it is not helpful and may be harmful.

The weight of evidence supporting each recommendation is classified as follows:

- Level A: Multiple populations evaluated. Data derived from multiple randomized clinical trials or meta-analyses.
- Level B: Limited populations evaluated. Data derived from a single randomized trial or nonrandomized studies.
- Level C: Very limited populations evaluated. Only consensus opinion of experts, case studies, or standard of care.

The following recommendations for AECG are included in the guideline:

Class I

- AECG is indicated when there is a need to clarify the diagnosis by detecting arrhythmias, QT interval changes, T-wave alternans, or ST changes, to evaluate risk, or to judge therapy. *(Level of Evidence: A)*
- Event monitors when symptoms are sporadic to establish whether or not they are caused by transient arrhythmias. *(Level of Evidence: B)*
- Implantable recorders are useful in patients with sporadic symptoms suspected to be related to arrhythmias such as syncope when a symptom-rhythm correlation cannot be established by conventional diagnostic techniques. *(Level of Evidence: B)*

The ACC/AHA/ESC guidelines for the management of patients with supraventricular arrhythmias states, “Ambulatory 24-hour Holter recording can be used in patients with frequent (i.e., several episodes per week) but transient tachycardias. An event or wearable loop recorder is often more useful than a 24-hour recording in patients with less frequent arrhythmias. Implantable loop recorders may be helpful in selected cases with rare symptoms (i.e., fewer than two episodes per month) associated with severe symptoms of hemodynamic instability” (Blomstrom-Lundqvist, et al., 2003). There have been no updates to this guideline since 2003.

The ACC/AHA clinical competence statement on electrocardiography and ambulatory electrocardiography states that the indications for ambulatory ECG were addressed in the 1999 clinical guidelines (Crawford, et al., 1999). The competence statement states there are no specific guidelines that distinguish patients for whom it is appropriate to perform continuous monitoring from those for whom intermittent ambulatory monitoring is

adequate. However, when monitoring is performed to evaluate the cause of intermittent symptoms, the frequency of symptoms should dictate the type of recording (Kadish, 2001).

Heart Rhythm Society (HRS)/European Heart Rhythm Association (EHRA)/ European Cardiac Arrhythmia Society (ECAS)
In a consensus statement on ablation of atrial fibrillation, the HRS, in collaboration with the ACC and other professional organizations, states that arrhythmia monitoring can be performed with the use of noncontinuous or continuous ECG monitoring tools. Choice of either method depends on individual need and consequence of arrhythmia detection. More intensive monitoring is associated with a greater likelihood of detecting both symptomatic and asymptomatic atrial fibrillation (AF). Available non-continuous detection tools include scheduled or symptom-initiated standard ECGs, Holter (24 hours to 7 days) and transtelephonic recordings, patient and automatically activated devices and external loop recorders. The guideline states that "ECGs should be obtained at all follow-up visits after ablation. More intense monitoring should be mainly driven by the clinical impact of AF detection with strict monitoring being necessary (e.g. in patients with thromboembolic risk factors for determining the adequate anticoagulation approach). Frequent ECG recording using a manually activated event recorder and counseling patients to take their pulse to monitor for irregularity may serve as initial screening tools for asymptomatic AF episodes. A one- to seven-day Holter monitor is an effective way to identify frequent asymptomatic recurrences of AF. A four-week auto-trigger event monitor, mobile cardiac outpatient telemetry system, or implantable subcutaneous monitor may identify less frequent AF" (Calkins, et al., 2012).

European Society of Cardiology (ESC)
ESC guidelines for the management of atrial fibrillation state "the intensity and duration of monitoring should be determined by the clinical need to establish the diagnosis, and should be driven mainly by the clinical impact of AF detection". The authors report that "in patients with suspected AF, a 12-lead ECG is recommended as the first step to establish the diagnosis. Clinical symptoms such as palpitations or dyspnea should trigger ECG monitoring to demonstrate AF, or to correlate symptoms with the underlying rhythm. There are only limited data comparing the value of different monitoring strategies. More intense and prolonged monitoring is justified in highly symptomatic patients, patients with recurrent syncope, and patients with a potential indication for anticoagulation (especially after cryptogenic stroke). In selected patients, implantation of a leadless AF monitoring device may be considered to establish the diagnosis." The authors report that "indications for AF monitoring in patients with previously diagnosed AF differ compared with undiagnosed patients. When arrhythmia or therapy-related symptoms are suspected, monitoring using Holter recordings or external event recorders should be considered. In patients with rhythm or rate control treatment and without further arrhythmia- or therapy-related symptoms, a 12-lead ECG should be recorded at regular intervals. In patients receiving antiarrhythmic drug therapy, the frequency of 12-lead ECG recording depends on the type of antiarrhythmic drug treatment, the potential side effects, complications, and risks of proarrhythmia." The 2012 focused update of this guideline did not discuss ECG monitoring (Camm, et al., 2010; 2012).

The European Society of Cardiology (ESC)
Task Force guidelines for the diagnosis and management of syncope, updated in 2009, include recommendations for electrocardiographic monitoring. The guideline states that currently several systems of ECG ambulatory monitoring are available: conventional ambulatory Holter monitoring, in-hospital monitoring, event recorders, external or implantable loop recorders, and remote (at home) telemetry. Remote (at home) telemetry is not in the electrocardiographic monitoring recommendations. The guideline states that the potential role of the remote telemetry systems in the diagnostic work-up of patients with syncope needs to be further evaluated (Moya, et al, 2009). There has been no update to this guideline since 2009.

Summary
The peer-reviewed medical literature and the American College of Cardiology/American Heart Association (ACC/AHA) practice guidelines for ambulatory electrocardiography (AECG) support the clinical utility of standard cardiac event monitors.

There is a lack of evidence in the published peer-reviewed medical literature supporting the clinical utility of long-term continuous external unattended cardiac monitoring devices. Studies are required to evaluate how long-term continuous external unattended cardiac monitoring devices can change treatment management and improve health outcomes compared to standard cardiac event monitors.

There is insufficient evidence in the published peer-reviewed medical literature supporting the clinical utility of external mobile outpatient cardiac telemetry systems. Many of the studies lack a comparator and do not report long-term outcomes. Additional studies with long-term follow-up are required to evaluate how external mobile outpatient cardiac telemetry systems can change treatment management and improve health outcomes compared to standard cardiac event monitors.

There is a lack of evidence in the published peer-reviewed medical literature supporting the clinical utility of an intracardiac ischemia monitoring system for any indication. Presently, there are no U.S. Food and Drug Administration (FDA)-approved intracardiac ischemia monitoring systems.

A self-monitoring combination device that includes an ECG monitor combined with a cellular telephone or other device or additional software or hardware required for downloading ECG data to a device such as personal computer, smart phone, or tablet are considered a convenience and not medically necessary for any indication.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Continuous 24- to 48-hour External Unattended Cardiac Monitoring Device

Covered when medically necessary to report 24- to 48-hour continuous external unattended cardiac monitoring device (e.g., Holter monitor™ [HM]):

CPT®* Codes	Description
93224	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; includes recording, scanning analysis with report, physician review and interpretation
93225	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; recording (includes connection, recording, and disconnection)
93226	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; scanning analysis with report
93227	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; physician review and interpretation

Patient or Event Recorder (Loop Recorder)

Covered when medically necessary to report external loop recorder:

CPT®* Codes	Description
93268	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, physician review and interpretation
93270	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)
93271	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 download and analysis

93272	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; physician review and interpretation

Covered when medically necessary to report implantable loop recorder:

CPT®* Codes	Description
33282	Implantation of patient-activated cardiac event recorder
33284	Removal of an implantable, patient-activated cardiac event recorder
93285	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 physician analysis, review and report; implantable loop recorder system
93291	Interrogation device evaluation (in person) with physician analysis, review and report, includes connection, recording and disconnection per patient encounter; implantable loop recorder system, including heart rhythm derived data analysis
93297	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, physician analysis, review(s) and report(s)
93298	Interrogation device evaluation(s), (remote) up to 30 days; implantable loop recorder system, including analysis of recorded heart rhythm data, physician analysis, review(s) and report(s)
93299	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

HCPCS Codes	Description
C1764	Event recorder, cardiac (implantable)
E0616	Implantable cardiac event recorder with memory, activator and programmer

External Mobile Outpatient Cardiac Telemetry System

Experimental/Investigational/Unproven/Not Covered to report an external mobile outpatient cardiac telemetry system:

CPT®* Codes	Description
93228	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; physician review and interpretation with report
93229	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 physician prescribed transmission of daily and emergent data reports

Experimental/Investigational/Unproven/Not Covered:

CPT®* Codes	Description
0295T	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
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)
0297T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; scanning analysis with report
0298T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; review and interpretation
0302T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; complete system (includes device and electrodes)
0303T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; electrode only
0304T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; device only
0305T	Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report
0306T	Interrogation device evaluation (in person) of intracardiac ischemia monitoring system with analysis, review, and report
0307T	Removal of intracardiac ischemia monitoring device
E1399†	Durable medical equipment, miscellaneous

†**Convenience/Not Medically Necessary/Not Covered when used to report the use of additional software or hardware required for downloading data to a device, self-monitoring combination devices.**

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