



Medical Coverage Policy

Effective Date.....10/15/2021
Next Review Date.....10/15/2022
Coverage Policy Number 0547

Ambulatory External and Implantable Electrocardiographic Monitoring

Table of Contents

Overview 1
 Coverage Policy..... 1
 General Background.....2
 Medicare Coverage Determinations 18
 Coding/Billing Information..... 18
 References38

Related Coverage Resources

[Tilt Table Testing](#)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses the use of ambulatory electrocardiographic monitoring in the evaluation of patients with suspected arrhythmias, unexplained episodes of syncope and/or cryptogenic stroke.

Coverage Policy

Ambulatory External Cardiac Monitoring

Ambulatory external cardiac monitoring from 48 hours to 30 days (Current Procedural Terminology [CPT®] codes 93241–93248, 93268, 93270, 93271, 93272, 0497T, 0498T) is considered medically necessary when EITHER of the following criteria are met:

- symptoms of presyncope, syncope, or severe palpitations when there is clinical suspicion of a significant bradyarrhythmia or tachyarrhythmia

- evaluation of atrial fibrillation for rhythm and/or rate control when the results will directly impact clinical decision-making

Ambulatory external cardiac monitoring from 48 hours to 30 days is considered not medically necessary for ANY other indication including ST segment analysis.

Mobile Cardiac Monitoring with Telemetry

Mobile cardiac outpatient telemetry (MCOT or MCT) (CPT codes 93228, 93229) is considered medically necessary when Holter monitoring is non-diagnostic or symptoms occur so infrequently and unpredictably that the length of the monitoring period would likely be inadequate to capture a diagnostic electrocardiogram (ECG) rhythm disorder and EITHER of the following criteria are met:

- symptoms of presyncope, syncope, or severe palpitations when there is clinical suspicion of a significant bradyarrhythmia or tachyarrhythmia
- evaluation of atrial fibrillation for rhythm and/or rate control when the results will directly impact clinical decision-making

Mobile cardiac monitoring is considered not medically necessary for ANY other indication.

Ambulatory Implantable Cardiac Event Monitoring

An implantable electrocardiographic event monitor (i.e., implantable loop recorder) (CPT code 33285; Healthcare Common Procedure Coding System [HCPCS] Code C1764, E0616) is considered medically necessary for the evaluation of an unexplained syncopal episode and/or cryptogenic stroke when a cardiac arrhythmia is suspected and EITHER of the following criteria are met:

- ambulatory external cardiac monitoring using a U.S. Food and Drug Administration (FDA) approved device failed to establish a definitive diagnosis
- ambulatory external cardiac monitoring is not expected to be diagnostic because the symptoms occur so infrequently and unpredictably that the length of the monitoring period would likely be inadequate to capture a diagnostic electrocardiogram (ECG) rhythm disorder

The replacement of an implantable electrocardiographic event monitor is considered medically necessary for an individual who continues to meet ALL of the above criteria and the existing monitor is no longer under warranty and cannot be repaired (e.g., device is nearing the end of its battery life).

The use of an implantable electrocardiographic event monitor (i.e., implantable loop recorder) for ANY other indication including routine monitoring of a documented arrhythmia or assessing the effectiveness of arrhythmia treatment is considered experimental, investigational or unproven.

Cardiac Self-Monitoring

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

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

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 symptoms such as

palpitations, weakness, dizziness, or syncope other patients may have no symptoms at all. Cardiac arrhythmias can be serious and life threatening and can lead to stroke and heart failure, including atrial fibrillation (AF), sustained ventricular tachycardia (VT), ventricular fibrillation, supraventricular tachycardia (SVT), sinus bradycardia/pauses and atrioventricular (AV) block. A history and physical examination may detect an arrhythmia and suggest possible causes. However, a diagnosis requires a 12-lead electrocardiography (ECG) or, less reliably, a rhythm strip, preferably obtained during symptoms to establish the relationship between symptoms and rhythm (Mitchell, 2021; Yenikomshian, et al., 2019).

Ambulatory electrocardiographic (ECG) monitoring provides data over an extended period of time. The most common use of ambulatory electrocardiographic monitoring is for the diagnosis and assessment of cardiac arrhythmias, conduction abnormalities (symptomatic or asymptomatic) or the presence of potential arrhythmias (such as in patients with syncope or presyncope). The choice of initial ambulatory ECG monitoring for the symptomatic patient depends on the frequency and severity of symptoms. Continuous ECG (Holter) monitoring for 24 to 48 hours is used to monitor patients with daily or near daily symptoms, while those with less frequent symptoms are more likely to benefit from extended monitoring. Extended ambulatory monitoring can be performed using an external monitoring device or an insertable cardiac monitor (Madias, 2020; Mittal, et al., 2011).

There are various ambulatory ECG monitoring techniques and systems. The devices used for ambulatory cardiac monitoring include:

- Holter monitors continuously record all ECG data for a period of 24–48 hours
- Patch monitors continuously record an ECG for up to 14 days
- Event monitors may be worn continuously or applied during symptoms for up to 30 days and include post event monitors, event/loop monitors and auto-triggered event recorders
- Mobile cardiac outpatient telemetry monitors are worn continuously and are capable of real-time streaming, transmitting a loop, or a single-event electrogram directly to the reading center through a wireless link for up to 30 days
- Insertable cardiac monitors (ICM's) are implanted in the left pectoral region and store events when the device is activated automatically according to programmed criteria or triggered by the patient

Ambulatory External Cardiac Monitoring

Ambulatory external cardiac monitoring devices provide recording of the electrical activity of the heart for more than 48 hours and up to 30 days. These devices are suggested to increase the detection of arrhythmias. A physician analyzes the recording to identify heart rhythm abnormalities. The devices used for ambulatory external cardiac monitoring for over 48 hours include patch monitors, event monitors and mobile cardiac outpatient telemetry.

Patch Monitors: Patch monitors are small adhesive devices that do not require separate leads, wires, or battery packs. Patch monitors are capable of continuously recording an ECG for up to 14 days. An example of these devices is the Zio® Patch (iRhythm Technologies, Inc., San Francisco, CA), which can record up to 14 days of activity. The Zio® Patch device requires placing a patch on the left pectoral region. There is a button on the patch which the individual can press to mark a symptomatic episode although the patch does not require activation. At the end of the recording period the individual sends the device to the physician for analysis. According to the manufacturer, the Zio patch is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, lightheadedness, presyncope, syncope, fatigue, or anxiety (iRhythm Technologies, 2020; Mittal, et al., 2011).

U.S. Food and Drug Administration (FDA): A number of ambulatory external continuous recording devices have been approved through the 510(k) process of the U.S. Food and Drug Administration (FDA) as Class II devices for extended ambulatory continuous ECG monitoring. The predicate devices upon which clearance was based are previous continuous ECG monitoring patches that can be worn for up to 14 days. The FDA does not necessarily require clinical data or outcome studies in making a determination of substantial equivalency for the purpose of device approval under section 510(k). There are several FDA-approved devices including, but not limited to: Zio Patch^{XT}, Cardia Solo, and the Carnation Ambulatory Monitor.

Literature Review – Patch monitors: There is evidence to support the clinical utility of ambulatory external continuous cardiac monitoring devices for 48 hours to 15 days in the diagnosis of cardiac arrhythmias in a specific subset of individuals (Barrett, et al., 2014; Schreiber, et al., 2014; Turakhia, et al., 2013; Rosenberg, et al., 2013).

Randomized Controlled Trials: Eysenck et al. (2020) conducted a randomized control trial (RCT) to evaluate the accuracy of atrial fibrillation (AF) detection by comparing four external ambulatory ECG monitors to permanent pacemaker AF detection. The Zio XT Monitor (ZM), NUUBO Vest (NV), Carnation Ambulatory Monitor (CAM) and Novacor 'R' Test 4 (RT) were all compared to a dual chamber rate adaptive permanent pacemaker (DDDRP PPM). Patients (n=21) with DDDRPPMs and a history of AF were included and wore every external cardiac monitor (ECM) for two weeks in randomized order. The mean study duration was 77 days. All 21 patients had an episode of AF at least once during the 14-day observation period. The primary outcomes measured the AF burden and individual AF episodes when comparing device ECGs to permanent pacemakers. The secondary outcomes measured patient acceptability, wear time, costs and time expenditure. A total of 1108 individual AF arrhythmia episodes were identified by DDDRPP pacemakers during the study. The Novacor 'R' Test 4 (RT) AF burden was significantly less accurate than the ZM, NV or CAM ($p < 0.05$). The RT had a significantly higher probability of inaccurate AF diagnosis than ZM or CAM ($p = 0.025$, $p = 0.042$; respectively). The ZM wear time was longer than the RT and patient acceptability was significantly greater for CAM than RT ($p = 0.024$). The authors concluded that the ZM, NV and CAM were more accurate in diagnosing atrial fibrillation compared to RT when using pacemaker AF arrhythmia episodes as the reference standard.

The early prolonged ambulatory cardiac monitoring in stroke (EPACS) study was an open-label randomized controlled trial conducted by Kaura et al. (2019) that compared a 14-day ECG monitoring patch (Zio® Patch, iRhythm Technologies) with short-duration Holter monitoring for the detection of paroxysmal atrial fibrillation (PAF) following a transient ischemic attack (TIA) or ischemic stroke. Patients (n=116) were included in the study if they were age ≥ 18 years and were diagnosed by a stroke physician or neurologist with an ischemic non-lacunar stroke or TIA within the past 72 hours. Patients with a TIA were enrolled only if there were cortical symptoms of hemianopia or dysphasia at presentation or if their diffusion-weighted cerebral MRI scan was positive in a non-lacunar distribution. Patients were randomly assigned to either the patch-based monitoring group (n=56) or the short-duration Holter monitoring group (n=60). Patients assigned to the conventional medical therapy arm received current medical therapy of ambulatory Holter monitoring only (duration determined by treating physician, which was usually 24 hours). Patients assigned to the patch-based monitoring arm had the patch applied to the anterior chest wall with the device kept on for 14-days and had standard practice of short-duration Holter monitoring. Patients in both study arms had follow-up at day 28 and 90 using electronic hospital medical records data search and a phone call to the patient's general practitioner in the community to collect endpoint data. End-point data included PAF documented on the ECG monitoring strategies or detected incidentally during usual clinical practice, such as during echocardiography. The study reported that patch-based monitoring strategy was significantly superior to short-duration Holter monitoring for the detection of PAF lasting 30 seconds or longer ($p = 0.026$). The rate of detection of PAF at 28 days was not clinically significant between the groups ($p = 0.05$). All patients who had newly diagnosed PAF were commenced on anticoagulation therapy by day 90. There was no difference in the rate of recurrent ischemic stroke/TIA or mortality ($p = 1.00$, $p = 0.48$; respectively) at 90 days. It was concluded that early, prolonged, patch-based monitoring after an index stroke or TIA is superior to short-duration Holter monitoring in the detection of PAF with an associated greater use of anticoagulation.

Steinhubl et al. (2018) conducted a randomized controlled trial that evaluated effectiveness of a home-based self-applied wearable electrocardiogram (ECG) patch on the detection of undiagnosed atrial fibrillation (AF). Patients (n=2659) at increased risk for AF were randomized to active home-based monitoring to start immediately (n=1364) or delayed by four months (n=1291). The study concluded that immediate monitoring using a self-applied ECG patch, compared with delaying ECG monitoring for four months, led to a significantly higher rate of AF diagnosis at four months (3.9% vs 0.9%).

Comparative Studies: Rho et al. (2018) conducted a prospective comparative study to compare two FDA-approved monitors: the Zio Patch Monitor, Zio-XT (iRhythm Technologies, Inc, San Francisco, CA) and the Carnation Ambulatory Monitoring, CAM (BDx, Inc, Seattle, WA). The primary outcome compared the ECG signal

clarity and determined whether there were differences in rhythm types diagnosed between the two monitors. The secondary outcome assessed whether variances in the findings on the CAM or Zio-XT resulted in differences in clinical decision making and assessed the ease of use and comfort of each monitor. Patients (n=30) referred to a community cardiology practice had both ambulatory external monitors (AEM's) placed with the intent of recording for seven days. After seven days, both monitors were returned to the manufacturer's reading center for processing and preparation of their standard ECG reports. During patch application and removal, a questionnaire to assess each device was completed by responsible medical technician. Additionally, the patients completed a questionnaire to assess both devices for comfort and ease of use. One patient was found to have no data recorded on the Zio-XT upon analysis by the Zio-XT reading center, and therefore, comparative ECG analysis was available for 29 of 30 patients. At the time of patch removal, both devices were considered user friendly. The CAM was slightly easier to attach and remove, was more stable, and was associated with less skin reaction. The patient experiences were comparable and favorable for both devices. When the managing physician was asked to recommend a specific clinical action based on the findings of each AEM separately, a difference in clinical decision making would have been made in 12 patients. The CAM recordings identified significantly more episodes of atrial tachycardia, atrial flutter, and nonsustained VT compared to the Zio-XT monitor ($p<0.001$, $p<0.002$, $p<0.001$; respectively). The CAM ECGs were ranked significantly higher in clarity compared to the Zio-XT ($p<0.001$). Differences in specific arrhythmias diagnosed between the two AEMs may result in differences in clinical decision making. Limitations reported included the small patient population, the study was not performed in a blinded fashion and the subjective nature of interpreting ECGs.

Several prospective reviews, have compared the 24 hour Holter monitor to 14-day adhesive patch monitor (i.e., Zio[®] Patch, carnation ambulatory monitor) for the evaluation of cardiac arrhythmias. Smith et al. (2017) compared simultaneous recordings from an external patch system specifically designed to ensure better P-wave recordings (Carnation Ambulatory Monitor) and standard Holter monitor to determine diagnostic efficacy. The authors noted that in all 50 patients, the P-wave centric patch recording system identified rhythms in 23 patients (46%) that altered management, compared to six Holter patients (12%), ($p<0.001$). The patch ECG intervals PR, QRS and QT correlated well with the Holter ECG intervals and 48 patients (96%) preferred wearing the patch monitor. Study results in this review indicated that single-channel ambulatory patch ECG monitor, designed specifically to ensure that the P-wave component of the ECG be visible, resulted in a significantly improved rhythm diagnosis and avoided inaccurate diagnoses made by the standard 3-channel Holter monitor. Barrett et al. (2014) compared a 24-hour Holter monitor to the Zio[®] Patch. Over the total wear time of both devices, the adhesive patch monitor detected 96 arrhythmia events compared with 61 arrhythmia events by the Holter monitor ($p<0.001$). In a 24 hour period, the Holter monitor detected significantly more of the six types of arrhythmia events than the adhesive patch monitor. The Holter monitor detected 61 arrhythmia events compared with 52 arrhythmia events by the adhesive patch monitor ($p=0.013$). A total of 93.7% patients found the adhesive patch monitor comfortable to wear and 81% indicated they would prefer it over the Holter monitor. Rosenberg et al. (2013) also compared a 24-hour Holter monitor to the Zio[®] Patch for the evaluation of patients currently undergoing the management of paroxysmal AF. The authors reported no difference in AF burden estimated by the Zio[®] Patch and the Holter monitor, AF events were identified in 18 additional individuals, and the documented pattern of AF (persistent or paroxysmal) changed in 21 patients after Zio[®] Patch monitoring. Other clinically relevant cardiac events recorded on the Zio[®] Patch after the first 24 hours of monitoring, including symptomatic ventricular pauses, prompted referrals for pacemaker placement or changes in medications. As a result of the findings from the Zio[®] Patch, 28.4% of patients had a change in their clinical management. It was concluded that the Zio[®] Patch was well tolerated, and allowed significantly longer continuous monitoring than a Holter, resulting in an improvement in clinical accuracy.

Technology Assessment: A Hayes Medical Technology Directory (2019) report evaluated the evidence (n=74–122,454 adults/8 studies; n=332–3209 children/2 studies) which assessed the following: Zio Patch monitoring in adults with an arrhythmia or a suspected arrhythmia (six studies); Zio Patch monitoring in asymptomatic adults who are at risk of developing an arrhythmia (two studies); and Zio Patch monitoring in children (two studies). The review included one randomized controlled trial with matched cohort study, three prospective studies and six retrospective studies evaluating Zio Patch monitoring in children and adults. Follow-up timeframes ranged from 90 days to one year. In general adults or children were included who were referred for ambulatory cardiac rhythm monitoring to evaluate a known arrhythmia, to identify potential arrhythmia(s) suggested by symptoms or for screening. Definitive patient selection criteria have not been established for the Zio Patch continuous ECG

monitor and the included studies did not provide adequate evidence to inform patient selection decisions. The most commonly reported adverse event was skin irritation which was mild in nature. A low-quality body of evidence in patients with known or suspected arrhythmias suggests continued detection of clinically significant arrhythmias (primarily AF) beyond 24 hours when using the Zio Patch monitoring system compared with another ECG monitoring system alone. There is insufficient evidence to draw conclusions regarding the clinical validity or utility of the Zio Patch in asymptomatic adults who are at risk of developing an arrhythmia or in children. The annual review in 2020 included four abstracts, (one randomized controlled trial, one prospective cohort study, one matched case-control study, and one systematic review) and did not identify any new evidence that would alter the existing findings (Hayes, 2019; updated 2020).

Event Monitors: An external cardiac event monitor is used for patients with less frequent (i.e., weekly to monthly) symptoms of palpitations, presyncope, or syncope. Event monitors can be worn continuously or applied during symptomatic events. When an event is detected, ECG data are stored for a predefined amount of time prior to the event (looping memory) and a period of time after activation (Madias, 2020; Steinberg, et al., 2017).

There are several types of event monitors:

- Post Event Monitoring devices are generally small, lightweight devices that can be placed on the patient's chest upon the onset of symptoms. The patient's rhythm is stored for a specified amount of time after recording begins (e.g., 30 to 150 seconds).
- Event/Loop Recorders are devices that constantly record for a pre-specified period, but do not save the data until they are triggered to do so by the patient pushing an event button. The device will record and save the patient's rhythm for a pre-specified amount of time before and after activation of the device (e.g., 30 seconds prior to and 60 seconds after the event).
- Auto-triggered Event Recorders are more advanced devices. In addition to recording and saving symptomatic patient-triggered events, these devices have auto-detect features that will capture asymptomatic arrhythmias based on detection algorithms (e.g., atrial fibrillation events or bradycardia events).

U.S. Food and Drug Administration (FDA)

There are numerous manufacturers of external cardiac event monitoring devices which can be found on the FDA Center for Devices and Radiologic Health 510(k) database (FDA, 2021). An example of an FDA approved external loop monitor is the King of Hearts Express[®] AF (Card Guard Scientific Survival). The FDA approval granted 510(k) approval on 4/5/2002. It is indicated for diagnostic evaluation of patients who experience transient dizziness, palpitations, syncope or chest pain (FDA, 2002).

Literature Review - Event Monitoring: Evidence in the peer-reviewed scientific literature and professional society recommendations supports the clinical utility of ambulatory external cardiac event monitoring. Evidence in the published literature consists of systematic reviews, case studies and few well-designed clinical trials (Callum, et al., 2020; Gladstone, et al., 2014; Sivakumaran, et al., 2003; Krahn, et al., 2001; Krahn, et al., 1999).

Randomized Controlled Trial: Gladstone et al. (2014) conducted a randomized controlled trial that evaluated if intensive ambulatory cardiac monitoring would increase the detection and treatment of atrial fibrillation in patients with unexplained stroke or TIA when compared to standard monitoring and follow-up. Patients (n=572) who had had a non-diagnostic cryptogenic ischemic stroke or TIA within the previous six months were randomly assigned to undergo ambulatory ECG monitoring with a 30-day event-triggered loop recorder (intervention group) (n=287) or an additional 24-hour Holter monitoring (control group) (n=285). Patients were included if they were 55 years of age or older, did not have known atrial fibrillation and had had an ischemic stroke or TIA of undetermined cause within the previous six months, diagnosed by a stroke neurologist after a standard workup, including 12-lead ECG, ambulatory ECG monitoring with the use of a Holter monitor for a minimum of 24 hours, brain and neurovascular imaging and echocardiography. The primary outcome measured newly detected atrial fibrillation lasting 30 seconds or longer within 90 days after randomization. Secondary outcomes measured episodes of atrial fibrillation lasting 2.5 minutes or longer and anticoagulation status at 90 days. The detection of atrial fibrillation was statistically significant in the intervention group for atrial fibrillation lasting 30 seconds or longer and atrial fibrillation lasting 2.5 minutes or longer (p<0.001). By 90 days, oral anticoagulant therapy had been prescribed significantly more for patients in the intervention group than in the control group (p=0.01). The authors

concluded that noninvasive ambulatory ECG monitoring for a target of 30 days significantly improved the detection of atrial fibrillation by a factor of more than five and nearly doubled the rate of anticoagulant treatment, as compared with the standard practice of short-duration monitoring.

Mobile cardiac outpatient telemetry: Mobile cardiac outpatient telemetry (MCOT) devices are similar to external event monitors, except that the data are transmitted wirelessly in real time to a monitoring center that is monitored 24 hours a day. The transmitted data may be from preprogrammed arrhythmias or patient activation. This offers the potential for real-time, immediate feedback to a healthcare provider for evaluation. MCOT is useful for patients with severe intermittent symptoms or if the differential diagnosis includes a potentially dangerous arrhythmia that should be diagnosed expeditiously. These devices are worn continuously and can be embedded in a patch, necklace pendant, or a chest belt carrier (Olgin, 2020; Shen, et al., 2017; Steinberg, et al., 2017).

U.S. Food and Drug Administration (FDA): Multiple MCOT devices have been approved by the U. S. Food and Drug Administration (FDA) through the Premarket Approval (PMA) process. Manufacturers of MCOT devices include, but are not limited to: CardioNet ambulatory ECG monitor with arrhythmia detection (San Diego, CA), HEARTLink™ II (Greensburg, PA) and LifeWatch Mobile Cardiac Telemetry 3 Lead LifeWatch MCT

Literature Review - Mobile cardiac outpatient telemetry: There is evidence to support the clinical utility of mobile cardiac outpatient telemetry in the diagnosis of cardiac arrhythmia in a specific subset of individuals (Derkac, et al., 2017; Favilla, et al., 2015).

Systematic Reviews: Sposato et al. (2015) conducted a systematic review and meta-analysis to estimate the proportion of newly diagnosed patients with atrial fibrillation after four sequential phases of cardiac monitoring following a stroke or transient ischemic attack. Fifty studies (n=11,658 patients) met the inclusion criteria. The criteria included studies that had the following diagnostic methods: admission ECG, serial ECG, continuous inpatient ECG monitoring, continuous inpatient cardiac telemetry, Holter monitoring, mobile cardiac outpatient telemetry, external loop recording, and implantable loop recording. The diagnostic methods were placed into four phases. Phase 1 was acute assessment in the emergency room which consisted of admission ECG. Phase 2 included the in-hospital stay and consisted of serial ECG, continuous inpatient ECG monitoring, continuous inpatient cardiac telemetry, and in-hospital Holter monitoring. The third phase was the first ambulatory period which consisted of ambulatory Holter monitoring. The fourth phase was the second ambulatory period which used long-term, sophisticated monitoring methods (usually after previous diagnostic attempts with similar methods) and consisted of mobile cardiac outpatient telemetry, external loop recording, and implantable loop recording. The proportion of patients diagnosed with post-stroke atrial fibrillation was 7.7% in phase 1, 5.1% in phase 2, 10.7% in phase 3 and 16.9% in phase 4. The overall atrial fibrillation detection yield after all phases of sequential cardiac monitoring was 23.7%. There were no differences (p=0.97) between the proportion of patients diagnosed with post-stroke atrial fibrillation by mobile cardiac outpatient telemetry, external loop recording, and implantable loop recording. The authors concluded that a combination of diagnostic methods could improve patient outcomes and guide future research.

Hoefman et al. (2010) published a systematic review on diagnostic tools for detecting cardiac arrhythmias. Descriptive and experimental studies were found. The studies compared the yield of two or more devices or diagnostic strategies. The authors reported that Holter monitors had less diagnostic yield (33–35%) than event recorders. Automatically triggered recorders detected the more arrhythmias (72–80%) than patient-triggered devices (17–75%). Implantable devices are used for prolonged monitoring periods in patients with infrequent symptoms or unexplained syncope. Combined analysis was not performed due to the heterogeneity of the study populations and study designs. The limitations in the evidence base precluded any specific recommendations on selection of devices. The authors reported that the choice of device should be driven largely by the presence, type, and frequency of symptoms experienced by each individual.

Retrospective Study: 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.

Professional Societies/Organizations

American College of Cardiology/American Heart Association/Heart Rhythm Society (ACC/AHA/HRS): The ACC/AHA/HRS guidelines on the evaluation and management of patients with bradycardia and cardiac conduction delay stated that because of the prolonged monitoring duration, external loop recorders, transtelephonic event recorders, adhesive patch recorders, and mobile continuous outpatient telemetry monitoring provide a higher diagnostic yield than 24- or 48-hour Holter monitoring. These extended monitoring strategies can be useful in the evaluation of suspected bradycardia or conduction disorders (Kusumoto, et al., 2018).

The ACC/AHA/HRS 2017 guideline for the evaluation and management of patients with syncope stated that there are several types of ambulatory cardiac rhythm monitoring devices. The selection and usefulness are highly dependent on the frequency of syncope and the likelihood of an arrhythmic cause of syncope. A patch recorder can be considered as an alternative to an external loop recorder in select ambulatory patients with syncope of suspected arrhythmic etiology. The guideline also stated that the patch is less cumbersome than an external loop recorder. Patient-activated, transtelephonic monitor (event monitor) can be used when there are frequent, spontaneous symptoms that are likely to recur within 2–6 weeks. There is limited use in patients with frank syncope associated with sudden incapacitation. An external loop recorder (patient or auto triggered) is selected when there is frequent, spontaneous symptoms related to syncope, which are likely to recur within 2–6 weeks. Mobile cardiac outpatient telemetry (MCOT) is used when there are spontaneous symptoms related to syncope and rhythm correlation. High-risk patients whose rhythm requires real-time monitoring can benefit from MCOT (Shen, et al., 2017).

International Society for Holter and Noninvasive Electrocardiology (ISHNE)/Heart Rhythm Society (HRS): The ISHNE and HRS consensus statement on ambulatory ECG and external cardiac monitoring/telemetry stated that accurate and timely diagnosis of arrhythmias is crucial to direct therapies that can have an important impact on diagnosis, prognosis or patient symptom status (Steinberg, et al., 2017).

The consensus statement made the following recommendations when selecting ambulatory ECG and external cardiac monitoring/telemetry:

- 24- to 48-hr Holter monitoring is recommended when frequent symptomatic events are anticipated to occur within the recording window
- Extended AECG monitoring (e.g., 15–30 days) is recommended when symptomatic event frequency is less than daily, or uncertain
- Continuous monitoring (1–14 days) is indicated to facilitate quantification and trending of arrhythmia burden and patterns (e.g., ventricular ectopy, sinus tachycardia)

Ambulatory Implantable Cardiac Event Monitoring

An implantable electrocardiographic event monitor, also referred to as an implantable loop recorder (ILR), is used to continuously monitor a patient's electrocardiogram for the detection of cardiac arrhythmias. ILRs are most commonly used in the evaluation of palpitations or syncope of undetermined etiology, particularly when symptoms are infrequent (e.g., less than once per month) and/or other ambulatory monitoring has been inconclusive. The goal is to capture the ECG at the time of the event and to distinguish a cardiac cause for transient loss of consciousness from other causes such as epilepsy, hypoglycemia, and transient ischemic attack (Benditt, et al., 2021; Hayes 2016).

ILRs are small leadless devices that are designed for subcutaneous implantation in the chest wall during a minimally-invasive surgical procedure. The preferred site for implantation is the left parasternal area of the chest. Sensing electrodes record a single-lead bipolar electrocardiogram (ECG), which can detect arrhythmias automatically or in response to patient activation. The episodes are recorded, stored and automatically transmitted wirelessly to the clinician through a cell phone, internet, or a patient monitor. According to the manufacturer, the battery has an estimated lifetime of 36–48 months. The device is removed when it is no longer needed, premature failure of the device or the battery is depleted. It may be replaced if clinically appropriate (Medtronic Inc, 2021; Galli, et al., 2016).

U.S. Food and Drug Administration (FDA): There are numerous manufacturers of ILR's which can be found in the FDA Center for Devices and Radiologic Health 510(k) database. Manufacturers of ILR devices include Abbott (Sylmar, CA), Biotronik (Lake Oswego, OR), Boston Scientific (Natick, MA), Sorin Group (Arvada, CO), Medtronic (Minneapolis, MN), Transoma Medical (St. Paul, MN) and St. Jude Medical (Sylmar, CA).

Ambulatory Implantable Cardiac Event Monitoring – Syncope: Syncope is a clinical syndrome characterized by transient loss of consciousness (TLOC) and postural tone, which can be caused by temporary cerebral hypoperfusion characterized by rapid onset, short duration, spontaneous, and complete resolution. When the initial evaluation, including history, physical examination, and ECG, are non-diagnostic in a patient with suspected syncope, the patient is considered to have an unexplained diagnosis (Bisignani, et al., 2018).

Literature Review – Syncope: The peer-reviewed medical literature supports the clinical utility of internal loop recorders. Evidence in the published literature primarily consists of systematic reviews and randomized controlled trials (Hindricks, et al., 2010; Giada, et al., 2007; Brignole, et al., 2006; Reiffel, et al., 2005; Farwell, et al., 2004; Sivakumar, et al., 2003).

Randomized Controlled Trials: Sulke et al. (2016) conducted a prospective randomized controlled trial (RCT) to evaluate the use of a remotely monitored implantable loop recorder (ILR) as the first line investigation in unexplained syncope. The ILR (Sleuth, Transoma Medical Inc.) was compared to conventional therapy and a dedicated syncope clinic (SC). The study included patients > age 16 years with normal complete blood count, urea, electrolytes and blood glucose who had more than two episodes of recurrent unexplained syncope (RUS) in last 24 months. Patients (n=246) were randomized into four groups: ILR alone group (n=66), ILR + SC group (n=59), SC group (n=60) or conventional treatment group (n=61). The syncope clinic included computed tomography (CT), magnetic resonance imaging (MRI), external loop monitoring (ELR), echocardiography, electrophysiological study, and standard implantable loop recorder implantation. All patients randomized to attend the syncope clinic (SC and ILR + SC) were offered tilt testing (HUT). The primary outcome measured the time to ECG diagnosis and the secondary outcome was the time to the second syncopal event after randomization. Median follow-up was 20 months with five patients withdrawing from the study after enrollment and four patients declining ILR implantation. The time to electrocardiogram (ECG) diagnosis was significantly shorter with the ILR alone group and SC group when compared to the conventional group (p=0.0004 and p=0.002, respectively). Seventy-four percent of the first syncopal events documented in the SC groups occurred during provocative tilt testing. Twenty-two percent of patients who received an ILR were found to have a bradycardia indication for permanent pacing, compared with 3% of patients who did not receive an ILR. Overall, more investigative tests were undertaken in the conventional group than in any other. Only patients who received an ILR had a significant increase in time to second syncope (p=0.02), suggesting successful diagnosis and management of treatable causes of syncope. There were no implant related complications. An author noted limitation was head-up tilt induced syncope may not be the same as the initial syncopal episode, questioning if SC with or without HUT is beneficial. The authors summarized that implantable loop recorders offered rapid diagnosis, increased the likelihood of syncope being reported, demonstrated a high rate of intermittent bradycardia requiring pacing and reduced recurrent syncope. Furthermore, conventional management of syncope failed to achieve an ECG diagnosis despite a large number of investigative tests. Syncope clinic and provocative tilt testing delivered a rapid ECG diagnosis, but did not prevent recurrent syncope.

Podoleanu et al. (2014) conducted a multicenter randomized open-label controlled trial (n=78) to evaluate the early use of an implantable loop recorder during a syncope evaluation. Patients were randomized into two groups. The ILR group (n=39) received a Reveal® or Reveal® Plus (Medtronic) ILR and the conventional (CONV) group (n=39) received a conventional evaluation commonly used by the attending physician, excluding the use of

an ILR. The study included patients presenting with an unexplained single, severe, and recent (≤ 6 months) syncope or patients having ≥ 2 unexplained syncopal episodes within the last 12 months. All syncopal events were unexplained by standard tests. The primary outcomes compared the diagnostic yield and costs of a common evaluation strategy for syncope with the early use of an ILR in low-risk patients and analyzed the quality of life (QoL) associated with the two strategies. The groups were followed for 14 months, with outpatient consultations scheduled at two, six, 10 and 14 months in the ILR group and at six and 14 months in the CONV group. After 14 months of follow-up, a certain cause of syncope was established in 18 (46.2%) patients in the ILR group and two (5%) patients in the CONV group ($p < 0.001$). Patients in the ILR group were hospitalized for a non-significantly shorter period than patients in the CONV group and advanced cardiology tests were performed less frequently in the ILR group than in the CONV group ($p = 0.05$). There was no difference between the two groups in terms of QoL. There were no adverse events related to syncope. Author noted limitations of the study included the small patient population and the cost of the device. It was concluded that in patients with unexplained syncope, the early use of an ILR has a superior diagnostic yield compared with the conventional strategy, and lower healthcare-related costs.

Da Costa et al. (2013) reported the results of a multicenter randomized prospective study that evaluated the clinical impact of the implantable loop recorder in patients with isolated syncope, bundle branch block (BBB) and a negative workup. Patients ($n = 78$) were randomized into two groups, ILR with the Reveal ILR ($n = 41$) or conventional strategy ($n = 37$) for 36 months. Patients were included if they experienced one syncopal episode associated with any type of BBB with a QRS greater or equal to 120 millisecond; no evidence of second or third-degree AV block; and negative workup including an electrophysiological study (EPS). The primary endpoint was the time to occurrence of syncopal events associated with arrhythmias. Patients in the ILR group had follow-up visits every three months until the first symptomatic or asymptomatic episode was documented by electrocardiogram or until 36 months. Patients in the conventional strategy group were seen in the outpatient department at three, six, 12, 15, 18, 21, 24, 27, 30 and 33 months after randomization and at the study completion (36 months). At each visit, arrhythmic or cardiovascular events were recorded and a 12-lead electrocardiogram was obtained. Additionally, at each visit a Holter monitor was used for seven days, with analyses performed using the R Test Evolution (RTE) event recorder. ILR documented events occurred in 15 out of 41 patients after a median of six months; 11 (26.8%) patients presented with third-degree AV block; three (7.3%) presented with sick sinus syndrome (sinus arrest); and one (2.4%) presented with ventricular tachycardia. In the conventional group, three (8.1%) patients presented with third-degree AV block and one (2.7%) presented with sick sinus syndrome, after a median of nine months. Overall, 21 patients (27%) developed significant arrhythmic events: ventricular tachycardia ($n = 1$; 1.3%); sudden death ($n = 2$; 2.6%); third-degree (AV) block ($n = 14$; 18%); and sick sinus syndrome ($n = 4$; 5.1%). There was a clinically significant difference in relevant arrhythmias between the ILR group ($n = 15/41$; 36.6%) and the conventional follow-up group ($n = 4/37$; 10.8%) ($p = 0.02$). Adverse events were not reported. Acknowledged study limitations included the small patient population, including patients after one episode of undiagnosed syncope and short term follow-up. The authors concluded this study demonstrated that ILR proved largely superior to conventional clinical follow-up in detecting recurrent events in patients with isolated syncope, BBB and negative EPS results, which may potentially impact therapeutic management.

Farwell et al. (2004) conducted a randomized controlled trial to investigate the effectiveness of the Reveal Plus ILR (Medtronic USA) compared to conventional treatment in the management of recurrent syncope. Patients ($n = 201$) were randomized to either the ILR group ($n = 103$) or conventional treatment group ($n = 98$). Included patients were aged 16 years or older, presented with acute syncope, a history of recurrent syncope (≥ 2) without a definite diagnosis following an initial clinical workup which included tilt-test and 24 hour Holter recording (if clinically indicated). The primary outcome measured was time to ECG diagnosis and the secondary outcome was the time to first and second recurrence of syncope following study induction. Additionally, the secondary outcome measured the time to the introduction of ECG guided therapy. The tertiary outcome measured the quality of life. The initial follow-up, which was at least six months, was extended to 18 months because there was not a reduction in syncopal events or an improvement in quality of life after six months. Three patients were lost to follow-up. In the Farwell et al., 2006 18-month follow-up the outcomes were reported on the patients ($n = 198$) that completed the study ($n = 101$ /ILR group; $n = 97$ /conventional treatment group). Patients in the ILR group received an ECG diagnosis in 43% of patients compared to 6% in the conventional treatment group ($p < 0.001$). Time to second syncope was significantly longer for ILR patients, although of borderline significance ($p = 0.04$). A greater variety of diagnoses and treatments were seen in ILR patients. ILR patients had fewer post-

randomization investigations and fewer days in hospital. There was a significant improved quality of life in the ILR group (visual analogue scales [VAS], $p=0.03$) for general wellbeing. Overall mortality was 12% with no difference between the two groups. There was no device related adverse events. It was noted that a limitation of the study was a decrease in sensitivity of the SF-12 and VAS questionnaires when used to assess quality of life in a syncopal population due to the rare and random nature of the symptom. The authors concluded that the ILR led to significantly more causes of syncope being diagnosed, rapid introduction of therapy and a greater variety of therapies being introduced.

Krahn et al. (2001) conducted a single-center crossover randomized controlled trial to compare diagnostic and clinical performance of ILR to standard testing in patients with unexplained syncope. Sixty patients were randomized to a "conventional" investigation strategy ($n=30$) or a prolonged monitoring strategy ($n=30$) with use of an ILR. Conventional testing included a 2–4 week period of monitoring with an external loop recorder, followed by tilt table testing and electrophysiological testing. If results were negative, patients immediately crossed over to ILR. Patients randomized to a prolonged monitoring strategy underwent implantation of a Reveal ILR (Medtronic). Patients were recruited if they had recurrent unexplained syncope or a single episode of syncope associated with injury that warranted cardiovascular investigation. After a clinical assessment patients were included in the study if they had negative results on Holter monitoring, no evidence of asymptomatic second- or third degree AV block, pauses > 3 seconds, sustained supraventricular tachycardia (SVT), or ≥ 10 beats of wide QRS complex tachycardia representative of ventricular tachycardia (VT). The outcomes measured syncope recurrence; diagnostic yield; infection at site of ILR implantation; treatment based on test findings and death. Patients were seen one week after loop recorder implantation for wound assessment and to reinforce patient understanding of the activation process. Subsequent follow-up occurred at one, two, three, six, nine and 12 months. Patients were seen immediately after a symptomatic event. A diagnosis was obtained in 14 of 27 (52%) patients randomized to prolonged monitoring compared to six of 30 (20%) patients undergoing conventional testing ($p=0.012$). Crossover ($n=6$) was associated with a diagnosis in one of six (17%) patients undergoing conventional testing compared to eight of 13 (62%) patients who completed monitoring ($p=0.069$). Overall, prolonged monitoring was more likely to result in a diagnosis than was conventional testing ($p=0.0014$). Bradycardia was detected in 14 patients undergoing monitoring compared with three patients undergoing conventional testing ($p=0.005$). There were no infections at the site of ILR implant. One patient in ILR group died of cerebrovascular accident at 10 months which was unrelated to study. Adverse events were not reported. Acknowledged limitations included the small patient population, selection bias, and using a single center for the study. The authors concluded that a prolonged monitoring strategy is more likely to provide a diagnosis than conventional testing in patients with unexplained syncope.

Systematic Reviews: A systematic review and meta-analysis of the literature (Solbiati, et al., 2017) analyzed the diagnostic yield of implantable loop recorders in patients with recurrent unexplained syncope in the absence of high-risk criteria and in high-risk patients after a negative evaluation. Prospective and retrospective studies with adults who underwent ILR implantation for undetermined syncope (49 studies; $n=4381$ patients) were included. The primary outcome was the overall diagnostic yield, defined as the proportion of patients with syncope recurrence and an available ILR recording or an automatic detection of a significant arrhythmia. Secondary outcomes were the proportions of patients with the specific etiologic diagnoses on the total of subjects and the proportion of an analyzable ECG recording during symptoms. The overall diagnostic yield was 43.9%. The proportions of subjects diagnosed with arrhythmic syncope, ventricular arrhythmias, supraventricular arrhythmias and bradyarrhythmias were 26.5%, 2.7%, 4.9% and 18.2%, respectively. The proportion of an analyzable ECG recording during symptoms was 89.5%. Median time to diagnosis was 134 days. The study concluded that about half of unexplained syncope subjects implanted with an ILR were diagnosed, and approximately 50% of them had an arrhythmia.

A Cochrane review of four randomized controlled trials (RCTs) ($n=579$ patients) by Solbiati et al. (2016) assessed the incidence of mortality, quality of life, adverse events and costs of ILRs versus conventional diagnostic workup in people with unexplained syncope. All randomized controlled trials of adult participants (i.e., ≥ 18 years old) with a diagnosis of unexplained syncope comparing ILR with standard diagnostic workup were included. The primary outcomes were short (i.e., within 30 days) and long-term all-cause mortality; other adverse events (cardiopulmonary resuscitation, intensive care unit admittance, major trauma, acute myocardial infarction, pulmonary embolism, major bleeding, aortic dissection ILR-related adverse events requiring either explant or treatment); and the quality of life during follow-up. The secondary outcomes were syncope relapse, economic

costs and etiological diagnosis. The author concluded that all-cause mortality (death from any cause) was no different in people who received the ILR. Loop recorders did not seem to change quality of life, although people with an ILR had a significantly higher rate of diagnosis compared to participants in the standard assessment group. Moreover, data seemed to show a trend towards a reduction in syncope recurrences after diagnosis in people implanted with ILR.

A Hayes Medical Technology Directory report on implantable cardiac loop recorders for the diagnosis and management of syncope in adults included 14 studies that evaluated the efficacy and safety of ILR implantation for recurrent syncope. The review included seven randomized controlled trials (RCTs) and seven observational cohort studies. Study sample sizes ranged from 60–939 patients. Included adult patients had unexplained, recurrent syncope or a suspicion of an underlying cardiac arrhythmia and structural heart disease, inherited cardiac condition or heart failure. Patients may have had negative or inconclusive results on standard tests that required confirmation or clarification. ILR results were compared to the results of standard tests (echocardiography, standard 12-lead ECG, 24-hour Holter monitoring, head-up tilt-table testing (TTT), electrophysiological (EPS) testing, external loop recorder (ELR), telemetry, etc.). Outcomes measured were diagnostic yield, syncope incidence and recurrence, treatment initiation based on ILR test results, outcomes of ILR-directed treatment for syncope, syncope-related trauma, quality of life, complications and mortality. Evidence from a moderate-quality body of evidence suggested that ILR is relatively safe. Additionally, when used as a part of a stepwise process, is superior to standard test strategies for patients with recurrent, unexplained syncope (RUS) and an inconclusive or negative diagnosis after initial clinical evaluation. The annual review in 2020, did not change the conclusions of the original review (Hayes, 2016).

Non-Comparative Studies: Iglesias et al. (2009) conducted a single-center prospective, cohort study that evaluated the clinical performance of ILR in patients with recurrent unexplained syncope (RUS) as part of a standardized stepwise diagnostic evaluation. The study included 939 patients who were referred for evaluation of RUS or presyncope or near syncope event. All patients underwent a stepwise evaluation including history, physical examination, electrocardiogram, head up tilt testing (HUTT), carotid sinus massage (CSM) and hyperventilation testing (HYV). Echocardiogram and stress test were performed when underlying heart disease was initially suspected. Electrophysiological study (EPS) and implantable loop recorder (ILR) were only used in patients with underlying structural heart disease or major unexplained syncope. Patients without a diagnosis after initial noninvasive tests (n=54) received the Reveal device (Medtronic Inc.). The primary outcome measured the diagnostic yield of the tests. A cause of syncope was identified in 66% of patients, including 27% vasovagal, 14% psychogenic, 6% arrhythmias, and 6% hypotension. Noninvasive testing identified 92% and invasive testing an additional 8% of the causes. HUTT yielded 38%, CSM 28%, HYV 49%, EPS 22%, and ILR 56% of diagnoses. Results suggest that the cause of syncope was identified in 66% of patients undergoing stepwise evaluation, including in 56% of patients with negative results on initial, noninvasive tests. An author noted limitation of the study included the absence of objective criteria for the diagnosis of psychogenic pseudo-syncope, which may have overestimated the true prevalence of this disorder. The study concluded that a standardized stepwise diagnostic evaluation focusing on noninvasive tests identified two-thirds of causes in patients referred to an ambulatory clinic for unexplained syncope.

Brignole et al. (2006) reported the results of a prospective multicenter observational study (ISSUE 2) that assessed the effectiveness of a diagnostic and treatment strategy in patients with recurrent suspected neurally mediated syncope (NMS). Patients (n=392) included were at least 30 years of age with three or more clinically severe syncopal episodes in the last two years without significant electrocardiographic and cardiac abnormalities. Phase I measured the time to first syncopal recurrence after ILR implantation. Phase II measured the rate and time of first syncopal recurrence; total burden of syncope after treatment initiation; multivariate analysis of predictors for syncope; cardiovascular event rate; death rate; trauma secondary to syncope recurrence; and the infection rate in ILR pocket. Follow-up occurred at three, six, 12, and 24 months. Among 392 patients, the one year recurrence rate of syncope during Phase I was 33%. One hundred and three patients had a documented episode and entered Phase II: 53 patients received specific therapy (pacemaker: 47, catheter ablation: four, implantable defibrillator: one, antiarrhythmic drug: one) and the remaining 50 patients did not receive specific therapy. The one year recurrence rate in 53 patients assigned to a specific therapy was 10% compared with 41% in the patients without specific therapy (p=0.002), and 92% for burden, (p=0.002). The one year recurrence rate in patients with pacemakers was 5%. During Phase I, severe trauma secondary to syncope relapse occurred in seven (2%) patients and mild trauma in 16 (4%) patients. During Phase II, no patient had

trauma. Finally, four patients had ILR pocket infections. An author noted limitation was the absence of a blinded control group. The study concluded that a strategy based on early diagnostic ILR application, with therapy delayed until documentation of syncope allows a safe, specific, and effective therapy in patients with NMS.

Professional Societies/Organizations

American College of Cardiology/American Heart Association/Heart Rhythm Society (ACC/AHA/HRS): The ACC/AHA/HRS guidelines on the evaluation and management of patients with bradycardia and cardiac conduction delay recommended that implantation of a cardiac monitor is reasonable if the initial noninvasive evaluation is nondiagnostic with infrequent symptoms (> 30 days between symptoms) and suspected to be caused by bradycardia (Kusumoto, et al., 2018).

The ACC/AHA/HRS 2017 guideline for the evaluation and management of patients with syncope stated that internal cardiac monitoring can be useful when evaluating selected ambulatory patients with syncope of suspected arrhythmic etiology (Shen, et al., 2017).

Ambulatory Implantable Cardiac Event Monitoring - Cryptogenic Stroke: A stroke occurs in approximately 800,000 people each year in the United States; it can be a devastating diagnosis, associated with high morbidity and mortality. The standard evaluation of a patient presenting with stroke includes a comprehensive physical examination, basic hematologic tests, assessment of cardiac rhythm with cardiac and neurologic imaging. Despite these efforts, a definitive cause for stroke cannot be identified in 10%–40% of patients; these patients are considered to have suffered a cryptogenic stroke. A significant proportion of cryptogenic stroke survivors may have underlying atrial fibrillation (AF) which can be difficult to diagnose with conventional monitoring strategies since the arrhythmia is commonly asymptomatic and often occurs sporadically (De Angelis, et al., 2020; Musat, et al., 2018; Ringwala, et al., 2016).

Literature Review - Cryptogenic Stroke: Evidence in prospective randomized controlled trials and observational studies support using ILR to detect atrial fibrillation in patients with cryptogenic stroke.

Randomized Controlled Trials: The Cryptogenic Stroke and Underlying AF (CRYSTAL AF) trial was a parallel group, randomized controlled trial conducted by Sanna et al. (2014) and compared the time to detection of atrial fibrillation using an implantable cardiac monitor or conventional follow-up in patients with cryptogenic stroke or transient ischemic attack (TIA). Patients (n=441) were randomized into two groups, the ICM group (Reveal XT; Medtronic) (n=221) or the control group (n=220). Patients assigned to the control group underwent assessment at scheduled and unscheduled visits, with ECG monitoring performed at the discretion of the site investigator. Patients eligible for the study were age 40 years and older without evidence of atrial fibrillation during at least 24 hours of ECG monitoring. Patients underwent randomization within 90 days after the index event that was supported by consistency between symptoms and findings on brain magnetic resonance imaging or computed tomography. Stroke was classified as cryptogenic after extensive testing did not reveal a clear cause. The primary end point was the time to first detection of atrial fibrillation (lasting > 30 seconds) within six months. Among the secondary end points was the time to first detection of atrial fibrillation within 12 months. Of the 441 randomly assigned patients, 416 (94.3%) completed six months of follow-up, two were lost to follow-up, five died, and 18 exited the study before six months. By six months, atrial fibrillation had been detected in 8.9% of patients in the ICM group (19 patients) versus 1.4% of patients in the control group (3 patients) (p<0.001). By 12 months, atrial fibrillation had been detected in 12.4% of patients in the ICM group (29 patients) versus 2.0% of patients in the control group (4 patients) (p<0.001). Of 208 ICMs that were inserted, five (2.4%) were removed due to infection at the insertion site or pocket erosion. The most common adverse events associated with the ICM were infection, pain and irritation or inflammation at the insertion site. The ICM remained inserted in 98.1% of patients at six months and in 96.6% of patients at 12 months.

In 2016, Brachmann et al. published the long-term results of the Cryptogenic Stroke and Underlying AF (CRYSTAL AF) trial which were collected ≤ 36 months after randomization. Cumulative AF detection rates in the ICM arm increased progressively during this period (30.0%), but remained low in the control arm (3.0%). Among ICM patients with AF detected, the median time to AF detection was 8.4 months, 81.0% of first AF episodes were asymptomatic, and 94.9% had at least one day with > 6 minutes of AF. At study closure, 379 patients had completed the 12-month visit (n=194 ICM; n=185 control), 177 patients had completed the 24-month visit (n=88 ICM; n=89 control), and 48 had completed the 36-month visit (n=24 ICM; 24 control). Acknowledged limitations

of the study included, uncertainty on whether the stroke was caused by atrial fibrillation, because not all cryptogenic strokes, are due to an arrhythmia. Additionally, the clinical significance of brief episodes of ICM detected atrial fibrillation is unknown and not all episodes of atrial fibrillation can be accounted for, because the device has a limited memory. Finally, the algorithm for detection of atrial fibrillation is not infallible, although the accuracy is reported to be 98.5%. The authors concluded that ECG monitoring with an ICM was superior to conventional follow-up for detecting atrial fibrillation after cryptogenic stroke.

In 2007, Giada et al. conducted a multicenter, prospective, randomized study to compare the diagnostic yield and the costs of an implantable loop recorder (ILR) with conventional treatment in patients with unexplained palpitations without severe structural heart disease. Patients (n=50) were randomized to conventional strategy (n=24) or to ILR implantation (n=26) with 1-year monitoring. Conventional treatment included 24 hour Holter recording, a four week period of ambulatory ECG monitoring with an external recorder, and electrophysiological study. The study included patients with infrequent (≤ 1 episode/month), sustained (> 1 minute) palpitations and a negative initial evaluation, including history, physical examination, and ECG. The primary end point was to establish the cause of the palpitations. A diagnosis was obtained in five patients in the conventional strategy group, and in 19 subjects in the ILR group ($p < 0.001$). Despite the higher initial cost, the cost per diagnosis in the ILR group was lower than in the conventional strategy group. No adverse events were observed. Author noted limitations to the study included the highly specific study population preventing the results from being generalized to the entire population with palpitations and the open label structure of the study. This study concluded that, in subjects with infrequent unexplained palpitations and without severe structural heart disease, ILR is a safe and cost-effective diagnostic approach.

Non-Comparative Study: Ritter et al. (2013) investigated whether implantation of an insertable cardiac monitor (ICM) is feasible in patients with cryptogenic stroke, and compared the intermittent atrial fibrillation (iAF) detection rate of the ICM with seven day Holter monitoring. Sixty patients with acute cryptogenic stroke were included. All patients had to have embolic stroke patterns on cerebral imaging. ICM (Reveal XT) was implanted 13 days after the qualifying event. Seven-day Holter was performed after the ICM was implanted. The outcomes measured were the diagnosis of AF, time to first AF and recurrent stroke. The iAF was detected by the ICM in ten patients (17%) at 12 months. Only one patient (1.7%) had iAF during seven day Holter monitoring ($P = 0.0077$). Episodes of iAF lasting two minutes or more were detected 64 days after implantation. There were no recurrent strokes during the observation period. The implantation procedure was well tolerated with no adverse events. The authors concluded that ICM implantation for the detection of iAF during outpatient follow-up is feasible in patients with cryptogenic stroke. ICMs offer a much higher diagnostic yield than seven day Holter monitoring.

Technology Assessment: A Hayes Technology Brief on implantable cardiac loop recorders for detection of atrial fibrillation following cryptogenic stroke included nine clinical studies (n=22–1247 patients) that evaluated ILRs for detection of atrial fibrillation (AF) following cryptogenic stroke. The review included a randomized controlled trial (RCT), a prospective cohort study, a retrospective database review, and six nested case-control studies. Overall, the quality of the evidence was moderate. Despite a number of poor-quality observational studies, a large, fair-quality randomized controlled trial (RCT) found that the ILR detected a higher number of AF events in patients with cryptogenic stroke compared with standard methods of monitoring. Results of the other studies, while of poor quality, had consistent findings suggesting that ILR detected AF in patients with a history of cryptogenic stroke. Use of the ILR in this patient population appears to be safe; the only reported complications included local irritation or infection. The annual review in 2019, did not change the conclusions of the original review (Hayes, 2017).

Professional Societies/Organizations

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

The 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation recommended that implantation of a cardiac monitor (loop recorder) is reasonable to optimize detection of silent AF in patients with cryptogenic stroke (i.e., stroke of unknown cause) in whom external ambulatory monitoring is inconclusive (January, et al, 2019).

Heart Rhythm Society (HRS): The HRS expert consensus statement on the diagnosis and treatment of postural tachycardia syndrome, inappropriate sinus tachycardia, and vasovagal syncope stated that implantable loop

recorders (ILRs) can be useful for assessing recurrent and troublesome syncope in older patients who lack a clear diagnosis and are at low risk of a fatal outcome (Sheldon, et al., 2015).

Ambulatory Implantable Cardiac Event Monitoring - Other Indications: An implantable electrocardiographic event monitor (i.e., implantable loop recorder) has been proposed for the treatment of multiple other disorders including: routine monitoring of documented arrhythmias or assessing the effectiveness of treatment.

ILR placement has been investigated as a tool to monitor for arrhythmias after a cardiac ablation and to guide anticoagulation. Surveillance for recurrence of atrial arrhythmias is important in patients who have undergone cardiac ablation. The optimal method for screening for episodes of AF after ablation is unknown (Lee and Mittal, 2018). However, serial or symptom-initiated standard ECGs, Holter monitoring (24 hours to 7 days) and transtelephonic recordings, patient-activated and automatically activated devices, and external loop recorders are among the commonly used noncontinuous monitoring tools. Although implantable loop recorders appear promising for the long-term assessment of AF burden, important limitations include less than 100% specificity due to myopotentials and atrial and ventricular premature beats, as well as limited memory, resulting in unretrievable electrograms that cannot be used to verify the correct rhythm diagnosis (Di Biase, et al., 2018; Ciconte, et al., 2017).

Postablation anticoagulation is recommended in all patients for at least two months. After this two-month period of mandatory oral anticoagulation, the anticoagulant regimen in place prior to the procedure is restarted. For those patients without evidence of recurrent AF and whose risk for embolization is very low, anticoagulation can be stopped (Passman, 2019; Di Biase, et al., 2018).

Literature Review – Other Indications

Randomized Controlled Trials: Mamchur et al. (2020) conducted a randomized controlled trial that evaluated the efficacy of noninvasive ambulatory ECG monitoring (NIAM) compared to implantable loop recorder (ILR) in patients undergoing a cardiac ablation for atrial fibrillation (AF). Thirty-two patients with AF were included in the study. Patients were randomized into two groups. Group I (n=15) received the Reveal XT ILR for invasive ECG monitoring for up to three months and group II (n=17) used the Spyder noninvasive ambulatory ECG monitoring (NIAM) for up to 14 days. Scheduled visits were planned for a period of 14 days and three months after implantation. Unscheduled visits occurred after documentation of at least two episodes recorded manually, or when indicating the presence of automatic records on the patient's assistant. The outcomes measured the detection of symptomatic and asymptomatic AF episodes, as well as symptomatic and asymptomatic episodes of other arrhythmias. In both groups, at least one AF episode was detected during 14 days of monitoring. The overall count of AF episodes was 25 in NIAM group and 28 in ILR group. The mean time between AF start and its registration by a physician was significantly higher in the NIAM group at eight hours compared to 20 hours in ILR group (p=0.005). The NIAM group had a sensitivity of 80.1%, specificity of 73.1%, positive predictive value of 74.1%, and negative predictive value of 79.2%. Corresponding values for the ILR group were 78.6%, 69%, 71%, and 77%. At the same time, continued monitoring with ILR for longer than two weeks did not lead to a significant change in the sensitivity and specificity of the method. An author noted limitation was that both methods were compared in different patient groups instead of simultaneous ECG recording of both types of devices in the same patients. The author concluded that in patients with paroxysmal AF, the diagnostic value of both NIAM and ILR is comparable. An increase in the duration of ECG monitoring for longer than two weeks does not provide additional diagnostic information.

Kapa et al. (2013) conducted a prospective, randomized trial (ABACUS study) to evaluate utility of an implantable loop recorder (ILR; Reveal XT, Medtronic, Inc) versus conventional monitoring (30-day transtelephonic monitors at discharge and after five months) for assessing arrhythmia burden and patient management post AF ablation. After AF ablation, patients (n=44) received ICMs and conventional monitoring. Conventional monitoring (CM) was monitored for 12 months which included wearing a monitor over three separate 30-day periods over the first year post-ablation and daily pulse checks. The conventional monitoring strategy was used for the first six months post-ablation. During the next six months, patients were monitored using the data from the Reveal device, transmitted from home every 30 days. The ILR was explanted in four patients. Over a mean follow-up of 6±1 months, 28 of the remaining 40 pts (70%) experienced AF (most within six weeks after ablation), which was correctly detected by ILR in 27 (96%) and by CM in 16 pts (57%). Patients with AF recurrences detected by both ILR and CM had a significantly higher AF burden than those with AF

recurrences detected by ILR only ($p < 0.05$). In eight patient (20%) ILR misclassified sinus rhythm with frequent premature atrial/ventricular complexes as AF. Additionally, signal under-sensing resulted in ILR rhythm misclassification as asystole or bradycardia in 10 patients (25%). ILR did detect true bradycardia or asystole in six pts (15%) which resulted in pacemaker implant in two pts and drug modification in three patients.

Pokushalov et al. (2011) conducted a prospective, randomized study to identify the optimal treatment of patients with AF recurrences after the first ablation. Two hundred eighty-six patients with highly symptomatic, drug-refractory paroxysmal AF underwent ablation (circumferential pulmonary vein isolation with linear lesions) and were monitored with an implantable cardiac monitor (Reveal XT, Medtronic). Patients without AF recurrences during the three month postablation period were assigned to group 1; those with AF recurrences to group 2. Patients in group 2 were randomly assigned to group 3 or group 4. Group 3 patients were treated only with antiarrhythmic drugs for six weeks, with no early reablation during the three month postablation period. In the case of AF recurrence after the 3-month postablation period, patients underwent reablation. Group 4 patients were treated according to the onset mechanism of AF recurrences, as detected and stored by the implantable cardiac monitor: antiarrhythmic drug therapy, but no reablation if AF was not preceded by triggers; early reablation if premature atrial beats or atrial tachycardia's or flutter triggered AF. The measured outcome this study was to identify the most appropriate strategy for treating patients with AF recurrences after the first ablation, through the diagnostic data stored by a subcutaneous AF monitor. All patients were followed up for one year to assess maintenance of sinus rhythm in each group. On 12-month follow-up examination, of the 119 (42%) patients in group 1, 112 (94%) had no AF recurrences. Among the 83 patients in group 3, only 27 (33%) had no recurrences. Of the 84 group 4 patients, 67 (80%) had no AF recurrences ($p < 0.0001$ versus group 3). Author noted limitations included small patient population and the usual definition for failures (>30 seconds of AF) was not used, which could result in a different result.

Evidence in the published, peer-reviewed scientific literature is inadequate to support improved clinical outcomes. A majority of the studies lack control groups, large sample populations, and measurement of long-term outcomes, therefore no conclusions can be made regarding the safety and efficacy of an implantable loop recorder to treat these conditions.

Professional Societies/Organizations

Heart Rhythm Society/European Heart Rhythm Association/European Cardiac Arrhythmia Society/ Asia Pacific Heart Rhythm Society/Latin American Society of Cardiac Stimulation and Electrophysiology.

(HRS/EHRA/ECAS/APHS/SOLAECE): The 2017 HRS/EHRA/ECAS/APHS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation recommended that arrhythmia monitoring for efficacy of catheter ablation is typically delayed for at least three months postablation unless required to evaluate arrhythmia symptoms during the early postablation period. The two main reasons to perform arrhythmia monitoring following catheter ablation are clinical care and as part of a clinical research trial.

Additionally, the consensus statement recommended that adherence to atrial fibrillation anticoagulation guidelines is recommended for patients who have undergone an AF ablation procedure, regardless of outcome of the procedure. If anticoagulation is needed for more than two months post ablation, the patient's stroke risk profile should be used and not the perceived success or failure of the ablation procedure (Calkins, et al., 2017).

Cardiac Self-Monitoring

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).

Literature Review – Cardiac Self-Monitoring: Koh et al. (2021) conducted a randomized controlled trial that evaluated smartphone electrocardiogram for detecting atrial fibrillation after a cerebral ischemic event. Patients (n=203) were randomized to undergo one additional 24-h Holter monitoring (control group, n=98) or 30-day smartphone ECG monitoring (intervention group, n=105) using KardiaMobile (AliveCorVR, Mountain View, CA, USA). Included patients were age \geq 55 years, not known to have AF and had an ischemic stroke or TIA of undetermined cause within the previous 12 months. The primary outcome measured the detection of one or more episodes of ECG-documented AF lasting 30 seconds or longer within three months after randomization. Detection of AF outside the monitoring period but within three months from randomization was also included. Secondary outcomes measured the usage of anticoagulation therapy at three months and the performance of KardiaMobile. AF lasting more than 30 seconds was detected in 10 of 105 patients in the intervention group and two of 98 patients in the control group (p=0.024). After the 30-day smartphone monitoring, there was a significantly higher proportion of patients on oral anticoagulation therapy at three months compared with baseline in the intervention group (p=0.002). Author noted limitations included using a single-lead ECG to monitor for AF and even though the secondary outcome showed a significantly higher number of patients prescribed anticoagulation therapy in the intervention group, the proportion of patients on anticoagulation therapy was not statistically significantly different at three months when compared between the two groups. No health disparities were identified by the investigators.

In 2020 Hayes, Inc. published an evidence analysis research brief evaluating patient use of mobile medical applications for the detection of cardiac arrhythmias. The review included 24 abstracts, including one randomized controlled trial (RCT), one prospective comparative study, seven prospective controlled studies, three prospective uncontrolled studies, two retrospective comparative studies, three retrospective controlled studies, four retrospective uncontrolled studies, one systematic review, one meta-analysis and one literature review. Rhythm data was collected by a variety of app users including clinicians, pharmacists, and patients across multiple care settings including intensive care units, interventional cardiology labs, pharmacies, and outpatient centers. Hayes concluded that there is sufficient published evidence to evaluate this technology. The study abstracts present conflicting findings regarding mobile medical apps (MMAs) for patient use in detecting cardiac arrhythmias. The overall the findings are conflicting for improvement of health outcomes, and until reviewed further conclusions regarding the safety and effectiveness could not be made.

Use Outside of the US

The European Society of Cardiology (ESC) guidelines for the diagnosis and management of syncope, updated in 2018, included recommendations for implantable loop recorders. ILR is recommended during an early phase of evaluation in patients with recurrent syncope of uncertain origin, absence of high-risk criteria and a high likelihood of recurrence within the battery life of the device. ILR is indicated in patients with high-risk criteria (e.g., new onset chest pain, palpitations, syncope during exertion, severe structural or coronary artery disease) when a comprehensive evaluation does not demonstrate a cause of syncope or lead to a specific treatment, and without conventional indications for primary prevention ICD or pacemaker indication. ILR should be considered in patients with suspected or certain reflex syncope presenting with frequent or severe syncopal episodes. Additionally, ESC recommended that ILR may be considered in patients in whom epilepsy was suspected but the treatment has proven ineffective and in patients with unexplained falls (Brignole, et al., 2018).

ESC guidelines for the management of atrial fibrillation developed in collaboration with European Association for Cardio-Thoracic Surgery (EACTS) recommended that non-invasive ECG monitors or implanted loop recorders be considered to document silent atrial fibrillation in stroke patients. The guideline recommended that oral anticoagulation after catheter ablation should follow the general anticoagulation recommendations, regardless of the presumed rhythm outcome. According to the guidelines, the patient should be seen at least once in the first 12 months after ablation. If there are symptomatic recurrences, further options should be explored (Kirchhof, et al., 2016).

European Heart Rhythm Association (EHRA), Heart Rhythm Society (HRS), and Asia Pacific Heart Rhythm Society (APHRS) guidelines for the management of patients with ventricular arrhythmias (VAs) addressed the indications for diagnostic testing, the present state of prognostic risk stratification, and the treatment strategies that have been demonstrated to improve the clinical outcome of patients with VAs. The consensus recommendations on general diagnostic work-up stated that prolonged ECG monitoring by Holter ECG, prolonged ECG event monitoring, or implantable loop recorders should be considered when documentation of further, potentially longer arrhythmias would change management (Pedersen, et al., 2014).

The National Institute for Health and Clinical Excellence (NICE) (United Kingdom) clinical guideline on transient loss of consciousness ('blackouts') for patients aged 16 years or older stated that for people with a suspected cardiac arrhythmic cause of syncope, the type of ambulatory ECG offered should be chosen on the basis of the person's history (and, in particular, frequency) of TLoC. For people who experience TLoC infrequently (less than once every two weeks), offer an implantable event recorder (NICE, 2010; updated 2016).

The National Institute for Health and Clinical Excellence (NICE) (United Kingdom) diagnostics guidance on Lead-I ECG devices for detecting symptomatic atrial fibrillation using single time point testing in primary care stated that there is a lack of evidence to recommend the routine adoption of lead-I electrocardiogram (ECG) devices (imPulse, Kardia Mobile, MyDiagnostick and Zenicor-ECG) to detect atrial fibrillation when used for single time point testing in primary care for people with signs or symptoms of the condition and an irregular pulse. Further research is needed to determine how using lead-I ECG devices in this way affects the number of people with atrial fibrillation detected, compared with current practice and how ECGs generated by the devices would be interpreted in practice, including staff time needed to interpret the ECG traces and associated costs (NICE, 2019).

The National Institute for Health and Clinical Excellence (NICE) (United Kingdom) Medtech innovation briefing guidance on KardiaMobile for the ambulatory detection of atrial fibrillation stated “there are key uncertainties that the evidence base for KardiaMobile involves different populations, in different settings and in different clinical scenarios. Also, the automated arrhythmia detection algorithm gave inconclusive results in between 0.8% and 27.6% of KardiaMobile ECGs” (NICE, 2020a).

In 2020, the National Institute for Health and Clinical Excellence (NICE) (United Kingdom) published a medical technologies guidance on the Zio XT for detecting cardiac arrhythmias. NICE stated that Zio XT is convenient and easy to wear, with an improved diagnostic yield when compared to standard 24-hour Holter monitoring. The “Zio XT is recommended as an option for people with suspected cardiac arrhythmias who would benefit from ambulatory electrocardiogram (ECG) monitoring for longer than 24 hours. The NHS organizations need to collect information on the resource use associated with using the Zio XT and the long-term consequences for those who use this monitoring (NICE 2020b).

Medicare Coverage Determinations

	Contractor	Policy Name/Number	Revision Effective Date
NCD	National	Electrocardiographic Services (20.15)	8/26/2004
LCD	First Coast Service Options, Inc.	Long-Term Wearable Electrocardiographic Monitoring (WEM) (L33380)	10/01/2019

Note: Please review the current Medicare Policy for the most up-to-date information.

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.

Ambulatory External Cardiac Monitoring

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
93241	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation
93242	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
93243	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report
93244	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation
93245	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation
93246	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
93247	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report
93248	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation
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, review and interpretation by a physician or other qualified health care professional
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 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; review and interpretation by a physician or other qualified health care professional
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 (Code deleted 12/31/2020)
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) (Code deleted 12/31/20)
0297T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; scanning analysis with report (Code deleted 12/31/2020)
0298T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; review and interpretation (Code deleted 12/31/2020)
0497T	External patient-activated, physician- or other qualified health care professional-prescribed, electrocardiographic rhythm derived event recorder without 24-hour attended monitoring; in-office connection
0498T	External patient-activated, physician- or other qualified health care professional-prescribed, electrocardiographic rhythm derived event recorder without 24-hour attended monitoring; review and interpretation by a physician or other qualified health care professional per 30 days with at least one patient-generated triggered event

ICD-10-CM Diagnosis Codes	Description
B33.20	Viral carditis, unspecified
B33.21	Viral endocarditis
B33.22	Viral myocarditis
B33.23	Viral pericarditis
B33.24	Viral cardiomyopathy
D15.1	Benign neoplasm of heart
D44.7	Neoplasm of uncertain behavior of aortic body and other paraganglia
D57.01	Hb-SS disease with acute chest syndrome
D73.5	Infarction of spleen
D86.85	Sarcoid myocarditis
D86.9	Sarcoidosis, unspecified
E05.00	Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm
E05.91	Thyrotoxicosis, unspecified with thyrotoxic crisis or storm
E06.3	Autoimmune thyroiditis
E06.9	Thyroiditis, unspecified
E42	Marasmic kwashiorkor
E72.12	Methylenetetrahydrofolate reductase deficiency
E75.21	Fabry (-Anderson) disease
E75.6	Lipid storage disorder, unspecified
E76.03	Scheie's syndrome
E78.71	Barth syndrome
E85.4	Organ-limited amyloidosis
E85.9	Amyloidosis, unspecified
E87.5	Hyperkalemia
E87.6	Hypokalemia
F10.239	Alcohol dependence with withdrawal, unspecified
F11.982	Opioid use, unspecified with opioid-induced sleep disorder
G40.001	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, with status epilepticus
G40.009	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, without status epilepticus
G40.011	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epilepticus
G40.019	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, without status epilepticus
G40.101	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, with status epilepticus
G40.109	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, without status epilepticus
G40.119	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus
G40.209	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, without status epilepticus
G40.219	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus
G40.309	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, without status epilepticus
G40.319	Generalized idiopathic epilepsy and epileptic syndromes, intractable, without status epilepticus
G40.A09	Absence epileptic syndrome, not intractable, without status epilepticus
G40.B09	Juvenile myoclonic epilepsy, not intractable, without status epilepticus
G40.419	Other generalized epilepsy and epileptic syndromes, intractable, without status epilepticus

ICD-10-CM Diagnosis Codes	Description
G40.509	Epileptic seizures related to external causes, not intractable, without status epilepticus
G40.802	Other epilepsy, not intractable, without status epilepticus
G40.804	Other epilepsy, intractable, without status epilepticus
G40.89	Other seizures
G40.901	Epilepsy, unspecified, not intractable, with status epilepticus
G40.909	Epilepsy, unspecified, not intractable, without status epilepticus
G40.919	Epilepsy, unspecified, intractable, without status epilepticus
G45.0	Vertebro-basilar artery syndrome
G45.2	Multiple and bilateral precerebral artery syndromes
G45.3	Amaurosis fugax
G45.4	Transient global amnesia
G45.8	Other transient cerebral ischemic attacks and related syndromes
G45.9	Transient cerebral ischemic attack, unspecified
G46.0	Middle cerebral artery syndrome
G46.1	Anterior cerebral artery syndrome
G46.2	Posterior cerebral artery syndrome
G46.3	Brain stem stroke syndrome
G46.4	Cerebellar stroke syndrome
G46.5	Pure motor lacunar syndrome
G46.6	Pure sensory lacunar syndrome
G46.7	Other lacunar syndromes
G47.30	Sleep apnea, unspecified
G47.31	Primary central sleep apnea
G47.33	Obstructive sleep apnea (adult) (pediatric)
G47.34	Idiopathic sleep related nonobstructive alveolar hypoventilation
G47.35	Congenital central alveolar hypoventilation syndrome
G47.37	Central sleep apnea in conditions classified elsewhere
G47.39	Other sleep apnea
G47.419	Narcolepsy without cataplexy
G71.01	Duchenne or Becker muscular dystrophy
G71.02	Facioscapulohumeral muscular dystrophy
G71.09	Other specified muscular dystrophies
G71.11	Myotonic muscular dystrophy
G83.20	Monoplegia of upper limb affecting unspecified side
G83.23	Monoplegia of upper limb affecting right nondominant side
G83.24	Monoplegia of upper limb affecting left nondominant side
G90.01	Carotid sinus syncope
G90.1	Familial dysautonomia [Riley-Day]
G90.3	Multi-system degeneration of the autonomic nervous system
H34.01	Transient retinal artery occlusion, right eye
H34.02	Transient retinal artery occlusion, left eye
H34.03	Transient retinal artery occlusion, bilateral
H34.10- H34.13	Central retinal artery occlusion
H34.211- H34.219	Partial retinal artery occlusion
H34.231- H34.239	Retinal artery branch occlusion
H34.9	Unspecified retinal vascular occlusion
H47.011- H47.019	Ischemic optic neuropathy

ICD-10-CM Diagnosis Codes	Description
H53.121	Transient visual loss, right eye
H53.122	Transient visual loss, left eye
H53.123	Transient visual loss, bilateral
H53.131- H53.139	Sudden visual loss
H53.2	Diplopia
H54.7	Unspecified visual loss
I05.0-I05.9	Rheumatic mitral valve diseases
I06.0-I06.8	Rheumatic aortic valve diseases
I07.0	Rheumatic tricuspid stenosis
I07.2	Rheumatic tricuspid stenosis and insufficiency
I07.8	Other rheumatic tricuspid valve diseases
I08.0	Rheumatic disorders of both mitral and aortic valves
I08.1	Rheumatic disorders of both mitral and tricuspid valves
I08.2	Rheumatic disorders of both aortic and tricuspid valves
I08.3	Combined rheumatic disorders of mitral, aortic and tricuspid valves
I11.0	Hypertensive heart disease with heart failure
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
I16.0-I16.9	Hypertensive crisis
I20.1	Angina pectoris with documented spasm
I21.01- I21.9	Acute Myocardial Infarction
I22.0-I22.9	Subsequent ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
I24.1	Dressler's syndrome
I25.111	Atherosclerotic heart disease of native coronary artery with angina pectoris with documented spasm
I25.41- I25.42	Coronary artery aneurysm and dissection
I25.5	Ischemic cardiomyopathy
I25.6	Silent myocardial ischemia
I25.701	Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris with documented spasm
I25.731	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.751	Atherosclerosis of native coronary artery of transplanted heart with angina pectoris with documented spasm
I25.791	Atherosclerosis of other coronary artery bypass graft(s) with angina pectoris with documented spasm
I26.01- I26.99	Pulmonary embolism
I27.0- I27.89	Other pulmonary heart diseases
I31.0	Chronic adhesive pericarditis
I31.1	Chronic constrictive pericarditis
I31.2	Hemopericardium, not elsewhere classified
I31.4	Cardiac tamponade
I32	Pericarditis in diseases classified elsewhere
I34.0	Nonrheumatic mitral (valve) insufficiency

ICD-10-CM Diagnosis Codes	Description
I34.1	Nonrheumatic mitral (valve) prolapse
I34.2	Nonrheumatic mitral (valve) stenosis
I34.9	Nonrheumatic mitral valve disorder, unspecified
I35.0	Nonrheumatic aortic (valve) stenosis
I35.1	Nonrheumatic aortic (valve) insufficiency
I35.2	Nonrheumatic aortic (valve) stenosis with insufficiency
I35.9	Nonrheumatic aortic valve disorder, unspecified
I36.0	Nonrheumatic tricuspid (valve) stenosis
I36.2	Nonrheumatic tricuspid (valve) stenosis with insufficiency
I37.2	Nonrheumatic pulmonary valve stenosis with insufficiency
I40.0-I40.9	Acute myocarditis
I41	Myocarditis in diseases classified elsewhere
I42.0-I42.9	Cardiomyopathy
I43	Cardiomyopathy in diseases classified elsewhere
I44.1	Atrioventricular block, second degree
I44.2	Atrioventricular block, complete
I44.4	Left anterior fascicular block
I44.5	Left posterior fascicular block
I44.7	Left bundle-branch block, unspecified
I45.0	Right fascicular block
I45.2	Bifascicular block
I45.3	Trifascicular block
I45.4	Nonspecific intraventricular block
I45.6	Pre-excitation syndrome
I45.81	Long QT syndrome
I46.2-I46.9	Cardiac arrest
I47.0-I47.9	Paroxysmal tachycardia
I48.0-I48.4	Atrial fibrillation and flutter
I49.01- I49.02	Ventricular fibrillation and flutter
I49.1	Atrial premature depolarization
I49.2	Junctional premature depolarization
I49.3	Ventricular premature depolarization
I49.40	Unspecified premature depolarization
I49.49	Other premature depolarization
I49.5	Sick sinus syndrome
I50.1-I50.9	Heart Failure
I51.0	Cardiac septal defect, acquired
I51.1	Rupture of chordae tendinae, not elsewhere classified
I51.2	Rupture of papillary muscle, not elsewhere classified
I51.3	Intracardiac thrombosis, not elsewhere classified
I51.4	Myocarditis, unspecified
I51.5	Myocardial degeneration
I51.81	Takotsubo syndrome
I5A	Non-ischemic myocardial injury (non-traumatic) (Code effective 10/01/2021)
I61.0	Nontraumatic intracerebral hemorrhage in hemisphere, subcortical
I61.1	Nontraumatic intracerebral hemorrhage in hemisphere, cortical
I61.2	Nontraumatic intracerebral hemorrhage in hemisphere, unspecified
I61.3	Nontraumatic intracerebral hemorrhage in brain stem
I61.4	Nontraumatic intracerebral hemorrhage in cerebellum
I61.5	Nontraumatic intracerebral hemorrhage, intraventricular

ICD-10-CM Diagnosis Codes	Description
I61.6	Nontraumatic intracerebral hemorrhage, multiple localized
I62.01	Nontraumatic acute subdural hemorrhage
I62.02	Nontraumatic subacute subdural hemorrhage
I62.03	Nontraumatic chronic subdural hemorrhage
I62.1	Nontraumatic extradural hemorrhage
I62.9	Nontraumatic intracranial hemorrhage, unspecified
I63.00- I63.19	Cerebral infarction
I63.20	Cerebral infarction due to unspecified occlusion or stenosis of unspecified precerebral arteries
I63.211	Cerebral infarction due to unspecified occlusion or stenosis of right vertebral artery
I63.212	Cerebral infarction due to unspecified occlusion or stenosis of left vertebral artery
I63.213	Cerebral infarction due to unspecified occlusion or stenosis of bilateral vertebral arteries
I63.22	Cerebral infarction due to unspecified occlusion or stenosis of basilar artery
I63.231	Cerebral infarction due to unspecified occlusion or stenosis of right carotid arteries
I63.232	Cerebral infarction due to unspecified occlusion or stenosis of left carotid arteries
I63.233	Cerebral infarction due to unspecified occlusion or stenosis of bilateral carotid arteries
I63.29	Cerebral infarction due to unspecified occlusion or stenosis of other precerebral arteries
I63.30- I63.49	Cerebral infarction
I63.511	Cerebral infarction due to unspecified occlusion or stenosis of right middle cerebral artery
I63.512	Cerebral infarction due to unspecified occlusion or stenosis of left middle cerebral artery
I63.513	Cerebral infarction due to unspecified occlusion or stenosis of bilateral middle cerebral arteries
I63.521	Cerebral infarction due to unspecified occlusion or stenosis of right anterior cerebral artery
I63.522	Cerebral infarction due to unspecified occlusion or stenosis of left anterior cerebral artery
I63.523	Cerebral infarction due to unspecified occlusion or stenosis of bilateral anterior cerebral arteries
I63.531	Cerebral infarction due to unspecified occlusion or stenosis of right posterior cerebral artery
I63.532	Cerebral infarction due to unspecified occlusion or stenosis of left posterior cerebral artery
I63.533	Cerebral infarction due to unspecified occlusion or stenosis of bilateral posterior cerebral arteries
I63.541	Cerebral infarction due to unspecified occlusion or stenosis of right cerebellar artery
I63.542	Cerebral infarction due to unspecified occlusion or stenosis of left cerebellar artery
I63.543	Cerebral infarction due to unspecified occlusion or stenosis of bilateral cerebellar arteries
I63.59	Cerebral infarction due to unspecified occlusion or stenosis of other cerebral artery
I63.81	Other cerebral infarction due to occlusion or stenosis of small artery
I63.89	Other cerebral infarction
I63.9	Cerebral infarction, unspecified
I65.01	Occlusion and stenosis of right vertebral artery
I65.02	Occlusion and stenosis of left vertebral artery
I65.03	Occlusion and stenosis of bilateral vertebral arteries
I65.1	Occlusion and stenosis of basilar artery
I65.21	Occlusion and stenosis of right carotid artery
I65.22	Occlusion and stenosis of left carotid artery
I65.23	Occlusion and stenosis of bilateral carotid arteries
I65.8	Occlusion and stenosis of other precerebral arteries
I66.01- I66.29	Occlusion and stenosis of cerebral arteries, not resulting in cerebral infarction
I66.3	Occlusion and stenosis of cerebellar arteries
I66.8	Occlusion and stenosis of other cerebral arteries
I67.0	Dissection of cerebral arteries, nonruptured
I67.3	Progressive vascular leukoencephalopathy
I67.4	Hypertensive encephalopathy

ICD-10-CM Diagnosis Codes	Description
I67.5	Moyamoya disease
I67.7	Cerebral arteritis, not elsewhere classified
I67.81	Acute cerebrovascular insufficiency
I67.82	Cerebral ischemia
I67.83	Posterior reversible encephalopathy syndrome
I68.0	Cerebral amyloid angiopathy
I68.2	Cerebral arteritis in other diseases classified elsewhere
I69.020	Aphasia following nontraumatic subarachnoid hemorrhage
I69.021	Dysphasia following nontraumatic subarachnoid hemorrhage
I69.120	Aphasia following nontraumatic intracerebral hemorrhage
I69.121	Dysphasia following nontraumatic intracerebral hemorrhage
I69.220	Aphasia following other nontraumatic intracranial hemorrhage
I69.221	Dysphasia following other nontraumatic intracranial hemorrhage
I69.310	Attention and concentration deficit following cerebral infarction
I69.311	Memory deficit following cerebral infarction
I69.312	Visuospatial deficit and spatial neglect following cerebral infarction
I69.313	Psychomotor deficit following cerebral infarction
I69.314	Frontal lobe and executive function deficit following cerebral infarction
I69.315	Cognitive social or emotional deficit following cerebral infarction
I69.318	Other symptoms and signs involving cognitive functions following cerebral infarction
I69.320	Aphasia following cerebral infarction
I69.321	Dysphasia following cerebral infarction
I69.322	Dysarthria following cerebral infarction
I69.323	Fluency disorder following cerebral infarction
I69.331	Monoplegia of upper limb following cerebral infarction affecting right dominant side
I69.332	Monoplegia of upper limb following cerebral infarction affecting left dominant side
I69.333	Monoplegia of upper limb following cerebral infarction affecting right non-dominant side
I69.334	Monoplegia of upper limb following cerebral infarction affecting left non-dominant side
I69.339	Monoplegia of upper limb following cerebral infarction affecting unspecified side
I69.341	Monoplegia of lower limb following cerebral infarction affecting right dominant side
I69.342	Monoplegia of lower limb following cerebral infarction affecting left dominant side
I69.343	Monoplegia of lower limb following cerebral infarction affecting right non-dominant side
I69.344	Monoplegia of lower limb following cerebral infarction affecting left non-dominant side
I69.349	Monoplegia of lower limb following cerebral infarction affecting unspecified side
I69.351	Hemiplegia and hemiparesis following cerebral infarction affecting right dominant side
I69.352	Hemiplegia and hemiparesis following cerebral infarction affecting left dominant side
I69.353	Hemiplegia and hemiparesis following cerebral infarction affecting right non-dominant side
I69.354	Hemiplegia and hemiparesis following cerebral infarction affecting left non-dominant side
I69.359	Hemiplegia and hemiparesis following cerebral infarction affecting unspecified side
I69.390	Apraxia following cerebral infarction
I69.391	Dysphagia following cerebral infarction
I69.392	Facial weakness following cerebral infarction
I69.393	Ataxia following cerebral infarction
I69.820	Aphasia following other cerebrovascular disease
I69.821	Dysphasia following other cerebrovascular disease
I72.0	Aneurysm of carotid artery
I72.5	Aneurysm of other precerebral arteries
I72.6	Aneurysm of vertebral artery
I73.00- I73.01	Raynaud's syndrome
I73.1	Thromboangiitis obliterans [Buerger's disease]

ICD-10-CM Diagnosis Codes	Description
I74.01	Saddle embolus of abdominal aorta
I74.09	Other arterial embolism and thrombosis of abdominal aorta
I74.10	Embolism and thrombosis of unspecified parts of aorta
I74.11	Embolism and thrombosis of thoracic aorta
I74.19	Embolism and thrombosis of other parts of aorta
I74.2	Embolism and thrombosis of arteries of the upper extremities
I74.3	Embolism and thrombosis of arteries of the lower extremities
I74.5	Embolism and thrombosis of iliac artery
I74.8	Embolism and thrombosis of other arteries
I77.1-I77.6	Other disorders of arteries and arterioles
I82.1	Thrombophlebitis migrans
I95.0	Idiopathic hypotension
I95.1	Orthostatic hypotension
I95.81- I95.89	Other hypotension
I97.0- I97.191	Intraoperative and postprocedural complications and disorders of circulatory system, not elsewhere classified
I97.710- I97.821	Intraoperative cardiac functional disturbances
M30.3	Mucocutaneous lymph node syndrome [Kawasaki]
M34.0- M34.9	Systemic sclerosis [scleroderma]
N28.0	Ischemia and infarction of kidney
O14.10- O14.15	Severe pre-eclampsia
O90.3	Peripartum cardiomyopathy
P28.4	Other apnea of newborn
P29.0- P29.89	Cardiovascular disorders originating in the perinatal period
Q20.0- Q20.8	Congenital malformations of cardiac chambers and connections
Q21.0- Q21.8	Congenital malformations of cardiac septa
Q22.0- Q22.8	Congenital malformations of pulmonary and tricuspid valves
Q23.0- Q23.8	Congenital malformations of aortic and mitral valves
Q24.0	Dextrocardia
Q24.2	Cor triatriatum
Q24.3	Pulmonary infundibular stenosis
Q24.4	Congenital subaortic stenosis
Q24.5	Malformation of coronary vessels
Q24.6	Congenital heart block
Q24.8	Other specified congenital malformations of heart
Q25.0	Patent ductus arteriosus
Q25.1	Coarctation of aorta
Q25.21	Interruption of aortic arch
Q25.29	Other atresia of aorta
Q25.3	Supravalvular aortic stenosis
Q25.41	Absence and aplasia of aorta
Q25.42	Hypoplasia of aorta

ICD-10-CM Diagnosis Codes	Description
Q25.43	Congenital aneurysm of aorta
Q25.44	Congenital dilation of aorta
Q25.45	Double aortic arch
Q25.46	Tortuous aortic arch
Q25.47	Right aortic arch
Q25.48	Anomalous origin of subclavian artery
Q25.49	Other congenital malformations of aorta
Q25.5	Atresia of pulmonary artery
Q25.6	Stenosis of pulmonary artery
Q25.71	Coarctation of pulmonary artery
Q25.72	Congenital pulmonary arteriovenous malformation
Q25.79	Other congenital malformations of pulmonary artery
Q26.0	Congenital stenosis of vena cava
Q26.2	Total anomalous pulmonary venous connection
Q26.3	Partial anomalous pulmonary venous connection
Q26.5	Anomalous portal venous connection
Q26.8	Other congenital malformations of great veins
Q67.6	Pectus excavatum
Q79.60- Q79.69	Ehlers-Danlos syndromes
Q85.1	Tuberous sclerosis
Q87.40	Marfan's syndrome, unspecified
Q87.410- Q87.418	Marfan's syndrome with cardiovascular manifestations
Q89.3	Situs inversus
Q90.0- Q90.9	Down syndrome
Q91.0	Trisomy 18, nonmosaicism (meiotic nondisjunction)
Q91.1	Trisomy 18, mosaicism (mitotic nondisjunction)
Q91.2	Trisomy 18, translocation
Q91.4	Trisomy 13, nonmosaicism (meiotic nondisjunction)
Q91.5	Trisomy 13, mosaicism (mitotic nondisjunction)
Q91.6	Trisomy 13, translocation
Q96.8	Other variants of Turner's syndrome
Q96.9	Turner's syndrome, unspecified
Q99.2	Fragile X chromosome
R00.0	Tachycardia, unspecified
R00.1	Bradycardia, unspecified
R00.2	Palpitations
R06.00	Dyspnea, unspecified
R06.02	Shortness of breath
R06.03	Acute respiratory distress
R06.81- R06.9	Other abnormalities of breathing
R07.1	Chest pain on breathing
R09.01- R09.02	Asphyxia and hypoxemia
R09.1	Pleurisy
R09.2	Respiratory arrest
R23.0	Cyanosis
R29.5	Transient paralysis

ICD-10-CM Diagnosis Codes	Description
R29.6	Repeated falls
R29.702	NIHSS score 2
R29.810	Facial weakness
R40.20	Unspecified coma
R40.4	Transient alteration of awareness
R41.0	Disorientation, unspecified
R41.3	Other amnesia
R41.82	Altered mental status, unspecified
R42	Dizziness and giddiness
R47.01	Aphasia
R47.02	Dysphasia
R47.1	Dysarthria and anarthria
R47.81	Slurred speech
R55	Syncope and collapse
R56.1	Post traumatic seizures
R56.9	Unspecified convulsions
R68.13	Apparent life threatening event in infant (ALTE)
R78.2	Finding of cocaine in blood
R93.1	Abnormal findings on diagnostic imaging of heart and coronary circulation
R94.31	Abnormal electrocardiogram [ECG] [EKG]
R94.39	Abnormal result of other cardiovascular function study
T86.290	Cardiac allograft vasculopathy
Z45.09	Encounter for adjustment and management of other cardiac device
Z48.21	Encounter for aftercare following heart transplant
Z82.41	Family history of sudden cardiac death
Z84.82	Family history of sudden infant death syndrome
Z86.73	Personal history of transient ischemic attack (TIA), and cerebral infarction without residual deficits
Z86.74	Personal history of sudden cardiac arrest
Z87.74	Personal history of (corrected) congenital malformations of heart and circulatory system
Z95.0	Presence of cardiac pacemaker
Z95.810	Presence of automatic (implantable) cardiac defibrillator

Considered Not Medically Necessary:

ICD-10-CM Diagnosis Codes	Description
	All other codes

Mobile Cardiac Monitoring with Telemetry

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

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; review and interpretation with report by a physician or other qualified health care professional

CPT® Codes	Description
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 transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional

ICD-10-CM Diagnosis Codes	Description
B33.20	Viral carditis, unspecified
B33.21	Viral endocarditis
B33.22	Viral myocarditis
B33.23	Viral pericarditis
B33.24	Viral cardiomyopathy
D15.1	Benign neoplasm of heart
D44.7	Neoplasm of uncertain behavior of aortic body and other paraganglia
D57.01	Hb-SS disease with acute chest syndrome
D73.5	Infarction of spleen
D86.85	Sarcoid myocarditis
D86.9	Sarcoidosis, unspecified
E05.00	Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm
E05.91	Thyrotoxicosis, unspecified with thyrotoxic crisis or storm
E06.3	Autoimmune thyroiditis
E06.9	Thyroiditis, unspecified
E42	Marasmic kwashiorkor
E72.12	Methylenetetrahydrofolate reductase deficiency
E75.21	Fabry (-Anderson) disease
E75.6	Lipid storage disorder, unspecified
E76.03	Scheie's syndrome
E78.71	Barth syndrome
E85.4	Organ-limited amyloidosis
E85.9	Amyloidosis, unspecified
E87.5	Hyperkalemia
E87.6	Hypokalemia
F10.239	Alcohol dependence with withdrawal, unspecified
F11.982	Opioid use, unspecified with opioid-induced sleep disorder
G40.001	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, with status epilepticus
G40.009	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, without status epilepticus
G40.011	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epilepticus
G40.019	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, without status epilepticus
G40.101	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, with status epilepticus
G40.109	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, without status epilepticus
G40.119	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus

ICD-10-CM Diagnosis Codes	Description
G40.209	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, without status epilepticus
G40.219	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus
G40.309	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, without status epilepticus
G40.319	Generalized idiopathic epilepsy and epileptic syndromes, intractable, without status epilepticus
G40.A09	Absence epileptic syndrome, not intractable, without status epilepticus
G40.B09	Juvenile myoclonic epilepsy, not intractable, without status epilepticus
G40.419	Other generalized epilepsy and epileptic syndromes, intractable, without status epilepticus
G40.509	Epileptic seizures related to external causes, not intractable, without status epilepticus
G40.802	Other epilepsy, not intractable, without status epilepticus
G40.804	Other epilepsy, intractable, without status epilepticus
G40.89	Other seizures
G40.901	Epilepsy, unspecified, not intractable, with status epilepticus
G40.909	Epilepsy, unspecified, not intractable, without status epilepticus
G40.919	Epilepsy, unspecified, intractable, without status epilepticus
G45.0	Vertebro-basilar artery syndrome
G45.2	Multiple and bilateral precerebral artery syndromes
G45.3	Amaurosis fugax
G45.4	Transient global amnesia
G45.8	Other transient cerebral ischemic attacks and related syndromes
G45.9	Transient cerebral ischemic attack, unspecified
G46.0	Middle cerebral artery syndrome
G46.1	Anterior cerebral artery syndrome
G46.2	Posterior cerebral artery syndrome
G46.3	Brain stem stroke syndrome
G46.4	Cerebellar stroke syndrome
G46.5	Pure motor lacunar syndrome
G46.6	Pure sensory lacunar syndrome
G46.7	Other lacunar syndromes
G47.30	Sleep apnea, unspecified
G47.31	Primary central sleep apnea
G47.33	Obstructive sleep apnea (adult) (pediatric)
G47.34	Idiopathic sleep related nonobstructive alveolar hypoventilation
G47.35	Congenital central alveolar hypoventilation syndrome
G47.37	Central sleep apnea in conditions classified elsewhere
G47.39	Other sleep apnea
G47.419	Narcolepsy without cataplexy
G71.01	Duchenne or Becker muscular dystrophy
G71.02	Facioscapulohumeral muscular dystrophy
G71.09	Other specified muscular dystrophies
G71.11	Myotonic muscular dystrophy
G83.20	Monoplegia of upper limb affecting unspecified side
G83.23	Monoplegia of upper limb affecting right nondominant side
G83.24	Monoplegia of upper limb affecting left nondominant side
G90.01	Carotid sinus syncope
G90.1	Familial dysautonomia [Riley-Day]
G90.3	Multi-system degeneration of the autonomic nervous system
H34.01	Transient retinal artery occlusion, right eye
H34.02	Transient retinal artery occlusion, left eye

ICD-10-CM Diagnosis Codes	Description
H34.03	Transient retinal artery occlusion, bilateral
H34.10- H34.13	Central retinal artery occlusion
H34.211- H34.219	Partial retinal artery occlusion
H34.231- H34.239	Retinal artery branch occlusion
H34.9	Unspecified retinal vascular occlusion
H47.011- H47.019	Ischemic optic neuropathy
H53.121	Transient visual loss, right eye
H53.122	Transient visual loss, left eye
H53.123	Transient visual loss, bilateral
H53.131- H53.139	Sudden visual loss
H53.2	Diplopia
H54.7	Unspecified visual loss
I05.0-I05.9	Rheumatic mitral valve diseases
I06.0-I06.8	Rheumatic aortic valve diseases
I07.0	Rheumatic tricuspid stenosis
I07.2	Rheumatic tricuspid stenosis and insufficiency
I07.8	Other rheumatic tricuspid valve diseases
I08.0	Rheumatic disorders of both mitral and aortic valves
I08.1	Rheumatic disorders of both mitral and tricuspid valves
I08.2	Rheumatic disorders of both aortic and tricuspid valves
I08.3	Combined rheumatic disorders of mitral, aortic and tricuspid valves
I11.0	Hypertensive heart disease with heart failure
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
I16.0-I16.9	Hypertensive crisis
I20.1	Angina pectoris with documented spasm
I21.01- I21.9	Acute Myocardial Infarction
I22.0-I22.9	Subsequent ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
I24.1	Dressler's syndrome
I25.111	Atherosclerotic heart disease of native coronary artery with angina pectoris with documented spasm
I25.41- I25.42	Coronary artery aneurysm and dissection
I25.5	Ischemic cardiomyopathy
I25.6	Silent myocardial ischemia
I25.701	Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris with documented spasm
I25.731	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.751	Atherosclerosis of native coronary artery of transplanted heart with angina pectoris with documented spasm
I25.791	Atherosclerosis of other coronary artery bypass graft(s) with angina pectoris with documented spasm

ICD-10-CM Diagnosis Codes	Description
I26.01- I26.99	Pulmonary embolism
I27.0- I27.89	Other pulmonary heart diseases
I31.0	Chronic adhesive pericarditis
I31.1	Chronic constrictive pericarditis
I31.2	Hemopericardium, not elsewhere classified
I31.4	Cardiac tamponade
I32	Pericarditis in diseases classified elsewhere
I34.0	Nonrheumatic mitral (valve) insufficiency
I34.1	Nonrheumatic mitral (valve) prolapse
I34.2	Nonrheumatic mitral (valve) stenosis
I34.9	Nonrheumatic mitral valve disorder, unspecified
I35.0	Nonrheumatic aortic (valve) stenosis
I35.1	Nonrheumatic aortic (valve) insufficiency
I35.2	Nonrheumatic aortic (valve) stenosis with insufficiency
I35.9	Nonrheumatic aortic valve disorder, unspecified
I36.0	Nonrheumatic tricuspid (valve) stenosis
I36.2	Nonrheumatic tricuspid (valve) stenosis with insufficiency
I37.2	Nonrheumatic pulmonary valve stenosis with insufficiency
I40.0-I40.9	Acute myocarditis
I41	Myocarditis in diseases classified elsewhere
I42.0-I42.9	Cardiomyopathy
I43	Cardiomyopathy in diseases classified elsewhere
I44.1	Atrioventricular block, second degree
I44.2	Atrioventricular block, complete
I44.4	Left anterior fascicular block
I44.5	Left posterior fascicular block
I44.7	Left bundle-branch block, unspecified
I45.0	Right fascicular block
I45.2	Bifascicular block
I45.3	Trifascicular block
I45.4	Nonspecific intraventricular block
I45.6	Pre-excitation syndrome
I45.81	Long QT syndrome
I46.2-I46.9	Cardiac arrest
I47.0-I47.9	Paroxysmal tachycardia
I48.0-I48.4	Atrial fibrillation and flutter
I49.01- I49.02	Ventricular fibrillation and flutter
I49.1	Atrial premature depolarization
I49.2	Junctional premature depolarization
I49.3	Ventricular premature depolarization
I49.40	Unspecified premature depolarization
I49.49	Other premature depolarization
I49.5	Sick sinus syndrome
I50.1-I50.9	Heart Failure
I51.0	Cardiac septal defect, acquired
I51.1	Rupture of chordae tendinae, not elsewhere classified
I51.2	Rupture of papillary muscle, not elsewhere classified
I51.3	Intracardiac thrombosis, not elsewhere classified

ICD-10-CM Diagnosis Codes	Description
I51.4	Myocarditis, unspecified
I51.5	Myocardial degeneration
I51.81	Takotsubo syndrome
I5A	Non-ischemic myocardial injury (non-traumatic) (Code effective 10/01/2021)
I61.0	Nontraumatic intracerebral hemorrhage in hemisphere, subcortical
I61.1	Nontraumatic intracerebral hemorrhage in hemisphere, cortical
I61.2	Nontraumatic intracerebral hemorrhage in hemisphere, unspecified
I61.3	Nontraumatic intracerebral hemorrhage in brain stem
I61.4	Nontraumatic intracerebral hemorrhage in cerebellum
I61.5	Nontraumatic intracerebral hemorrhage, intraventricular
I61.6	Nontraumatic intracerebral hemorrhage, multiple localized
I62.01	Nontraumatic acute subdural hemorrhage
I62.02	Nontraumatic subacute subdural hemorrhage
I62.03	Nontraumatic chronic subdural hemorrhage
I62.1	Nontraumatic extradural hemorrhage
I62.9	Nontraumatic intracranial hemorrhage, unspecified
I63.00- I63.19	Cerebral infarction
I63.20	Cerebral infarction due to unspecified occlusion or stenosis of unspecified precerebral arteries
I63.211	Cerebral infarction due to unspecified occlusion or stenosis of right vertebral artery
I63.212	Cerebral infarction due to unspecified occlusion or stenosis of left vertebral artery
I63.213	Cerebral infarction due to unspecified occlusion or stenosis of bilateral vertebral arteries
I63.22	Cerebral infarction due to unspecified occlusion or stenosis of basilar artery
I63.231	Cerebral infarction due to unspecified occlusion or stenosis of right carotid arteries
I63.232	Cerebral infarction due to unspecified occlusion or stenosis of left carotid arteries
I63.233	Cerebral infarction due to unspecified occlusion or stenosis of bilateral carotid arteries
I63.29	Cerebral infarction due to unspecified occlusion or stenosis of other precerebral arteries
I63.30- I63.49	Cerebral infarction
I63.511	Cerebral infarction due to unspecified occlusion or stenosis of right middle cerebral artery
I63.512	Cerebral infarction due to unspecified occlusion or stenosis of left middle cerebral artery
I63.513	Cerebral infarction due to unspecified occlusion or stenosis of bilateral middle cerebral arteries
I63.521	Cerebral infarction due to unspecified occlusion or stenosis of right anterior cerebral artery
I63.522	Cerebral infarction due to unspecified occlusion or stenosis of left anterior cerebral artery
I63.523	Cerebral infarction due to unspecified occlusion or stenosis of bilateral anterior cerebral arteries
I63.531	Cerebral infarction due to unspecified occlusion or stenosis of right posterior cerebral artery
I63.532	Cerebral infarction due to unspecified occlusion or stenosis of left posterior cerebral artery
I63.533	Cerebral infarction due to unspecified occlusion or stenosis of bilateral posterior cerebral arteries
I63.541	Cerebral infarction due to unspecified occlusion or stenosis of right cerebellar artery
I63.542	Cerebral infarction due to unspecified occlusion or stenosis of left cerebellar artery
I63.543	Cerebral infarction due to unspecified occlusion or stenosis of bilateral cerebellar arteries
I63.59	Cerebral infarction due to unspecified occlusion or stenosis of other cerebral artery
I63.81	Other cerebral infarction due to occlusion or stenosis of small artery
I63.89	Other cerebral infarction
I63.9	Cerebral infarction, unspecified
I65.01	Occlusion and stenosis of right vertebral artery
I65.02	Occlusion and stenosis of left vertebral artery
I65.03	Occlusion and stenosis of bilateral vertebral arteries
I65.1	Occlusion and stenosis of basilar artery
I65.21	Occlusion and stenosis of right carotid artery

ICD-10-CM Diagnosis Codes	Description
I65.22	Occlusion and stenosis of left carotid artery
I65.23	Occlusion and stenosis of bilateral carotid arteries
I65.8	Occlusion and stenosis of other precerebral arteries
I66.01- I66.29	Occlusion and stenosis of cerebral arteries, not resulting in cerebral infarction
I66.3	Occlusion and stenosis of cerebellar arteries
I66.8	Occlusion and stenosis of other cerebral arteries
I67.0	Dissection of cerebral arteries, nonruptured
I67.3	Progressive vascular leukoencephalopathy
I67.4	Hypertensive encephalopathy
I67.5	Moyamoya disease
I67.7	Cerebral arteritis, not elsewhere classified
I67.81	Acute cerebrovascular insufficiency
I67.82	Cerebral ischemia
I67.83	Posterior reversible encephalopathy syndrome
I68.0	Cerebral amyloid angiopathy
I68.2	Cerebral arteritis in other diseases classified elsewhere
I69.020	Aphasia following nontraumatic subarachnoid hemorrhage
I69.021	Dysphasia following nontraumatic subarachnoid hemorrhage
I69.120	Aphasia following nontraumatic intracerebral hemorrhage
I69.121	Dysphasia following nontraumatic intracerebral hemorrhage
I69.220	Aphasia following other nontraumatic intracranial hemorrhage
I69.221	Dysphasia following other nontraumatic intracranial hemorrhage
I69.310	Attention and concentration deficit following cerebral infarction
I69.311	Memory deficit following cerebral infarction
I69.312	Visuospatial deficit and spatial neglect following cerebral infarction
I69.313	Psychomotor deficit following cerebral infarction
I69.314	Frontal lobe and executive function deficit following cerebral infarction
I69.315	Cognitive social or emotional deficit following cerebral infarction
I69.318	Other symptoms and signs involving cognitive functions following cerebral infarction
I69.320	Aphasia following cerebral infarction
I69.321	Dysphasia following cerebral infarction
I69.322	Dysarthria following cerebral infarction
I69.323	Fluency disorder following cerebral infarction
I69.331	Monoplegia of upper limb following cerebral infarction affecting right dominant side
I69.332	Monoplegia of upper limb following cerebral infarction affecting left dominant side
I69.333	Monoplegia of upper limb following cerebral infarction affecting right non-dominant side
I69.334	Monoplegia of upper limb following cerebral infarction affecting left non-dominant side
I69.339	Monoplegia of upper limb following cerebral infarction affecting unspecified side
I69.341	Monoplegia of lower limb following cerebral infarction affecting right dominant side
I69.342	Monoplegia of lower limb following cerebral infarction affecting left dominant side
I69.343	Monoplegia of lower limb following cerebral infarction affecting right non-dominant side
I69.344	Monoplegia of lower limb following cerebral infarction affecting left non-dominant side
I69.349	Monoplegia of lower limb following cerebral infarction affecting unspecified side
I69.351	Hemiplegia and hemiparesis following cerebral infarction affecting right dominant side
I69.352	Hemiplegia and hemiparesis following cerebral infarction affecting left dominant side
I69.353	Hemiplegia and hemiparesis following cerebral infarction affecting right non-dominant side
I69.354	Hemiplegia and hemiparesis following cerebral infarction affecting left non-dominant side
I69.359	Hemiplegia and hemiparesis following cerebral infarction affecting unspecified side
I69.390	Apraxia following cerebral infarction
I69.391	Dysphagia following cerebral infarction

ICD-10-CM Diagnosis Codes	Description
I69.392	Facial weakness following cerebral infarction
I69.393	Ataxia following cerebral infarction
I69.820	Aphasia following other cerebrovascular disease
I69.821	Dysphasia following other cerebrovascular disease
I72.0	Aneurysm of carotid artery
I72.5	Aneurysm of other precerebral arteries
I72.6	Aneurysm of vertebral artery
I73.00- I73.01	Raynaud's syndrome
I73.1	Thromboangiitis obliterans [Buerger's disease]
I74.01	Saddle embolus of abdominal aorta
I74.09	Other arterial embolism and thrombosis of abdominal aorta
I74.10	Embolism and thrombosis of unspecified parts of aorta
I74.11	Embolism and thrombosis of thoracic aorta
I74.19	Embolism and thrombosis of other parts of aorta
I74.2	Embolism and thrombosis of arteries of the upper extremities
I74.3	Embolism and thrombosis of arteries of the lower extremities
I74.5	Embolism and thrombosis of iliac artery
I74.8	Embolism and thrombosis of other arteries
I77.1-I77.6	Other disorders of arteries and arterioles
I82.1	Thrombophlebitis migrans
I95.0	Idiopathic hypotension
I95.1	Orthostatic hypotension
I95.81- I95.89	Other hypotension
I97.0- I97.191	Intraoperative and postprocedural complications and disorders of circulatory system, not elsewhere classified
I97.710- I97.821	Intraoperative cardiac functional disturbances
M30.3	Mucocutaneous lymph node syndrome [Kawasaki]
M34.0- M34.9	Systemic sclerosis [scleroderma]
N28.0	Ischemia and infarction of kidney
O14.10- O14.15	Severe pre-eclampsia
O90.3	Peripartum cardiomyopathy
P28.4	Other apnea of newborn
P29.0- P29.89	Cardiovascular disorders originating in the perinatal period
Q20.0- Q20.8	Congenital malformations of cardiac chambers and connections
Q21.0- Q21.8	Congenital malformations of cardiac septa
Q22.0- Q22.8	Congenital malformations of pulmonary and tricuspid valves
Q23.0- Q23.8	Congenital malformations of aortic and mitral valves
Q24.0	Dextrocardia
Q24.2	Cor triatriatum
Q24.3	Pulmonary infundibular stenosis
Q24.4	Congenital subaortic stenosis

ICD-10-CM Diagnosis Codes	Description
Q24.5	Malformation of coronary vessels
Q24.6	Congenital heart block
Q24.8	Other specified congenital malformations of heart
Q25.0	Patent ductus arteriosus
Q25.1	Coarctation of aorta
Q25.21	Interruption of aortic arch
Q25.29	Other atresia of aorta
Q25.3	Supravalvular aortic stenosis
Q25.41	Absence and aplasia of aorta
Q25.42	Hypoplasia of aorta
Q25.43	Congenital aneurysm of aorta
Q25.44	Congenital dilation of aorta
Q25.45	Double aortic arch
Q25.46	Tortuous aortic arch
Q25.47	Right aortic arch
Q25.48	Anomalous origin of subclavian artery
Q25.49	Other congenital malformations of aorta
Q25.5	Atresia of pulmonary artery
Q25.6	Stenosis of pulmonary artery
Q25.71	Coarctation of pulmonary artery
Q25.72	Congenital pulmonary arteriovenous malformation
Q25.79	Other congenital malformations of pulmonary artery
Q26.0	Congenital stenosis of vena cava
Q26.2	Total anomalous pulmonary venous connection
Q26.3	Partial anomalous pulmonary venous connection
Q26.5	Anomalous portal venous connection
Q26.8	Other congenital malformations of great veins
Q67.6	Pectus excavatum
Q79.60- Q79.69	Ehlers-Danlos syndromes
Q85.1	Tuberous sclerosis
Q87.40	Marfan's syndrome, unspecified
Q87.410- Q87.418	Marfan's syndrome with cardiovascular manifestations
Q89.3	Situs inversus
Q90.0- Q90.9	Down syndrome
Q91.0	Trisomy 18, nonmosaic (meiotic nondisjunction)
Q91.1	Trisomy 18, mosaicism (mitotic nondisjunction)
Q91.2	Trisomy 18, translocation
Q91.4	Trisomy 13, nonmosaic (meiotic nondisjunction)
Q91.5	Trisomy 13, mosaicism (mitotic nondisjunction)
Q91.6	Trisomy 13, translocation
Q96.8	Other variants of Turner's syndrome
Q96.9	Turner's syndrome, unspecified
Q99.2	Fragile X chromosome
R00.0	Tachycardia, unspecified
R00.1	Bradycardia, unspecified
R00.2	Palpitations
R06.00	Dyspnea, unspecified
R06.02	Shortness of breath

ICD-10-CM Diagnosis Codes	Description
R06.03	Acute respiratory distress
R06.81- R06.9	Other abnormalities of breathing
R07.1	Chest pain on breathing
R09.01- R09.02	Asphyxia and hypoxemia
R09.1	Pleurisy
R09.2	Respiratory arrest
R23.0	Cyanosis
R29.5	Transient paralysis
R29.6	Repeated falls
R29.702	NIHSS score 2
R29.810	Facial weakness
R40.20	Unspecified coma
R40.4	Transient alteration of awareness
R41.0	Disorientation, unspecified
R41.3	Other amnesia
R41.82	Altered mental status, unspecified
R42	Dizziness and giddiness
R47.01	Aphasia
R47.02	Dysphasia
R47.1	Dysarthria and anarthria
R47.81	Slurred speech
R55	Syncope and collapse
R56.1	Post traumatic seizures
R56.9	Unspecified convulsions
R68.13	Apparent life threatening event in infant (ALTE)
R78.2	Finding of cocaine in blood
R93.1	Abnormal findings on diagnostic imaging of heart and coronary circulation
R94.31	Abnormal electrocardiogram [ECG] [EKG]
R94.39	Abnormal result of other cardiovascular function study
T86.290	Cardiac allograft vasculopathy
Z45.09	Encounter for adjustment and management of other cardiac device
Z48.21	Encounter for aftercare following heart transplant
Z82.41	Family history of sudden cardiac death
Z84.82	Family history of sudden infant death syndrome
Z86.73	Personal history of transient ischemic attack (TIA), and cerebral infarction without residual deficits
Z86.74	Personal history of sudden cardiac arrest
Z87.74	Personal history of (corrected) congenital malformations of heart and circulatory system
Z95.0	Presence of cardiac pacemaker
Z95.810	Presence of automatic (implantable) cardiac defibrillator

Considered Not Medically Necessary:

ICD-10-CM Diagnosis Codes	Description
	All other codes

Implantable electrocardiographic event monitor (implantable loop recorder)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming
0650T	Programming device evaluation (remote) of subcutaneous cardiac rhythm monitor system, with iterative adjustment of the implantable device to test the function of the device and select optimal permanently programmed values with analysis, review and report by a physician or other qualified health care professional (Code effective 07/01/2021)

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

Cardiac Self-Monitoring

Considered Convenience Item/Not Medically Necessary when used to report the use of additional software or hardware required for downloading ECG data to a device, combination devices, self-monitoring or other personal electronic device:

HCPCS Codes	Description
E1399	Durable medical equipment, miscellaneous

*Current Procedural Terminology (CPT®) ©2020 American Medical Association: Chicago, IL.

References

1. Albers GW, Bernstein RA, Brachmann J, Camm J, Easton JD, Fromm P, et al. Heart Rhythm Monitoring Strategies for Cryptogenic Stroke: 2015 Diagnostics and Monitoring Stroke Focus Group Report. J Am Heart Assoc. 2016 Mar 15;5(3):e002944.
2. Barrett PM, Komatireddy R, Haaser S, Topol S, Sheard J, Encinas J, et al. Comparison of 24-hour Holter monitoring with 14-day novel adhesive patch electrocardiographic monitoring. Am J Med. 2014 Jan;127(1):95.e11-7.
3. Benditt D. Syncope in adults: Clinical manifestations and diagnostic evaluation. In: UpToDate, Kowey P, Hockberger RS, Yeon SB (Eds). UpToDate, Waltham, MA. Literature review current through: July 2021. Topic last updated: April 28, 2021. Accessed August 25, 2021.
4. Bettin M, Dechering D, Kochhäuser S, Bode N, Eckardt L, Frommeyer G, Reinke F. Extended ECG monitoring with an implantable loop recorder in patients with cryptogenic stroke: time schedule, reasons for explantation and incidental findings (results from the TRACK-AF trial). Clin Res Cardiol. 2019 Mar;108(3):309-314.
5. Bisignani A, De Bonis S, Mancuso L, Ceravolo G, Bisignani G. Implantable loop recorder in clinical practice. J Arrhythm. 2018 Nov 20;35(1):25-32.
6. Bolourchi M, Batra AS. Diagnostic yield of patch ambulatory electrocardiogram monitoring in children (from a national registry). Am J Cardiol. 2015 Mar 1;115(5):630-4.
7. Brachmann J, Morillo CA, Sanna T, Di Lazzaro V, Diener HC, Bernstein RA, et al. Uncovering Atrial Fibrillation Beyond Short-Term Monitoring in Cryptogenic Stroke Patients: Three-Year Results From the

Cryptogenic Stroke and Underlying Atrial Fibrillation Trial. *Circ Arrhythm Electrophysiol.* 2016 Jan;9(1):e003333.

8. Brignole M, Moya A, de Lange FJ, Deharo JC, Elliott PM, Fanciulli A, et al. 2018 ESC Guidelines for the diagnosis and management of syncope. *Eur Heart J.* 2018 Jun 1;39(21):1883-1948.
9. Brignole M, Sutton R, Menozzi C, Garcia-Civera R, Moya A, Wieling W, et al.; International Study on Syncope of Uncertain Etiology 2 (ISSUE 2) Group. Early application of an implantable loop recorder allows effective specific therapy in patients with recurrent suspected neurally mediated syncope. *Eur Heart J.* 2006 May;27(9):1085-92.
10. Calkins H, Hindricks G, Cappato R, Kim YH, Saad EB, Aguinaga L, et al. 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation. *Heart Rhythm.* 2017 Oct;14(10):e275-e444.
11. Calkins H, Zipes DP. Hypotension and syncope. . In: Zipes DP, Libby P, Bonow RO, Mann DL, Tomaselli GF, Braunwald E, editors. *Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine.* 11th ed. Philadelphia, PA: Elsevier Inc; 2019. Ch 43.
12. Callum KJ, Hall L, Jack S, Farman C, Rushworth GF, Leslie SJ. External Loop Recorders: Primary Care Placement Is Noninferior to Hospital-Based Cardiac Unit. *J Prim Care Community Health.* 2020 Jan-Dec;11:2150132720946147.
13. Carrasco C, Golyan D, Kahen M, Black K, Libman RB, Katz JM. Prevalence and Risk Factors for Paroxysmal Atrial Fibrillation and Flutter Detection after Cryptogenic Ischemic Stroke. *J Stroke Cerebrovasc Dis.* 2018 Jan;27(1):203-209.
14. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determinations (LCDs) alphabetical index. Accessed August 25, 2021. Available at URL address: https://www.cms.gov/medicare-coverage-database/indexes/lcd-alphabetical-index.aspx?Cntrctr=373&ContrVer=1&CntrctrSelected=373*1&DocType=Active%7cFuture&s=All&bc=AggAAAQAAAA&
15. Centers for Medicare and Medicaid Services (CMS). National Coverage Determinations (NCDs) alphabetical index. Accessed August 25, 2021. Available at URL address: <https://www.cms.gov/medicare-coverage-database/indexes/ncd-alphabetical-index.aspx>
16. Cho HJ, Lee CH, Hwang J, Park HS, Choi SW, Kim IC, et al. Accuracy of implantable loop recorders for detecting atrial tachyarrhythmias after atrial fibrillation catheter ablation. *Int J Arrhythm.* 2020 April 21(6).
17. Ciconte G, Giacomelli D, Pappone C. The Role of Implantable Cardiac Monitors in Atrial Fibrillation Management. *J Atr Fibrillation.* 2017 Aug 31;10(2):1590.
18. Conti S, Reiffel JA, Gersh BJ, Kowey PR, Wachter R, Halperin JL, et al. Baseline Demographics, Safety, and Patient Acceptance of an Insertable Cardiac Monitor for Atrial Fibrillation Screening: The REVEAL-AF Study. *J Atr Fibrillation.* 2017 Feb 28;9(5):1551.
19. Cotter PE, Martin PJ, Ring L, et al. Incidence of atrial fibrillation detected by implantable loop recorders in unexplained stroke. *Neurology.* 2013; 80(17):1546-1550.
20. Da Costa A, Defaye P, Romeyer-Bouchard C, Roche F, Dauphinot V, Deharo JC, et al. Clinical impact of the implantable loop recorder in patients with isolated syncope, bundle branch block and negative workup: a randomized multicentre prospective study. *Arch Cardiovasc Dis.* 2013 Mar;106(3):146-54.

21. Daly M, Melton I, Crozier I. Implantable Cardiac Rhythm and Hemodynamic Monitors. In: Ellenbogen KA, Wilkoff BL, Kay GN, Lau CP, Auricchio A, editors. *Clinical Cardiac Pacing, Defibrillation and Resynchronization Therapy*, Fifth Edition. Elsevier, Ch 25.
22. Davtyan K, Shatakhtsyan V, Poghosyan H, Deev A, Tarasov A, Kharlap M, et al. Radiofrequency versus Cryoballoon Ablation of Atrial Fibrillation: An Evaluation Using ECG, Holter Monitoring, and Implantable Loop Recorders to Monitor Absolute and Clinical Effectiveness. *Biomed Res Int*. 2018 Mar 12;2018:3629384.
23. De Angelis MV, Di Stefano V, Franciotti R, Furla N, Di Girolamo E, Onofri M, et al. Cryptogenic stroke and atrial fibrillation in a real-world population: the role of insertable cardiac monitors. *Sci Rep*. 2020 Feb 24;10(1):3230.
24. Derkac WM, Finkelmeier JR, Horgan DJ, Hutchinson MD. Diagnostic yield of asymptomatic arrhythmias detected by mobile cardiac outpatient telemetry and autotrigger looping event cardiac monitors. *J Cardiovasc Electrophysiol*. 2017 Dec;28(12):1475-1478.
25. Di Biase L, Aagaard P, Santangeli P, Natale A. Cardiac Electrophysiology: From Cell to Bedside. In: Zipes, DP, Jalife J, Stevenson W. *Catheter Ablation: Clinical Aspects*. 7th ed. St. Louis, MO. Elsevier, Inc; 2018. Ch 124. Pages 1194-1210.
26. Etgen T, Hochreiter M, Mundel M, et al. Insertable cardiac event recorder in detection of atrial fibrillation after cryptogenic stroke: an audit report. *Stroke*. 2013; 44(7):2007-2009.
27. Eysenck W, Freemantle N, Sulke N. A Randomized Trial Evaluating the Accuracy of AF Detection by Four External Ambulatory ECG Monitors Compared to Permanent Pacemaker AF Detection *J Interv Card Electrophysiol*. Apr 2020; 57(3): 361-369.
28. Favilla CG, Ingala E, Jara J, Fessler E, Cucchiara B, Messé SR, Mullen MT, Prasad A, Siegler J, Hutchinson MD, Kasner SE. Predictors of finding occult atrial fibrillation after cryptogenic stroke. *Stroke*. 2015 May;46(5):1210-5.
29. Farwell DJ, Freemantle N, Sulke AN. Use of implantable loop recorders in the diagnosis and management of syncope. *Eur Heart J*. 2004 Jul;25(14):1257-63.
30. Farwell DJ, Freemantle N, Sulke N. The clinical impact of implantable loop recorders in patients with syncope. *Eur Heart J*. 2006 Feb;27(3):351-6.
31. Fung E, Järvelin MR, Doshi RN, Shinbane JS, Carlson SK, Grazette LP, Chang PM, Sangha RS, Huikuri HV, Peters NS. Electrocardiographic patch devices and contemporary wireless cardiac monitoring. *Front Physiol*. 2015 May 27;6:149.
32. Galli A, Ambrosini F, Lombardi F. Holter Monitoring and Loop Recorders: From Research to Clinical Practice. *Arrhythm Electrophysiol Rev*. 2016 Aug;5(2):136-43.
33. Giada F, Gulizia M, Francese M, Croci F, Santangelo L, Santomauro M, et al. Recurrent unexplained palpitations (RUP) study comparison of implantable loop recorder versus conventional diagnostic strategy. *J Am Coll Cardiol*. 2007 May 15;49(19):1951-6.
34. Gladstone DJ, Dorian P, Spring M, Panzov V, Mamdani M, Healey JS, et al. Atrial premature beats predict atrial fibrillation in cryptogenic stroke: results from the EMBRACE trial. *Stroke*. 2015; 46(4):936-941.
35. Gladstone DJ, Spring M, Dorian P, Panzov V, Thorpe KE, Hall J, Vaid H, et al. Atrial fibrillation in patients with cryptogenic stroke. *N Engl J Med*. 2014 Jun 26;370(26):2467-77.

36. Hayes, Inc. Evidence Analysis Research Brief. Patient Use of Mobile Medical Applications for Detection of Cardiac Arrhythmias. Hayes, Inc.; February 2020.
37. Hayes, Inc. Health Technology Brief. Implantable cardiac loop recorders for detection of atrial fibrillation following cryptogenic stroke. Hayes, Inc.; June 2017.
38. Hayes, Inc. Medical Technology Directory Report. Implantable cardiac loop recorders for diagnosis and management of syncope in adults. Hayes, Inc.; March 2016.
39. Hayes Inc. Health Technology Brief. Zio Patch (iRhythm Technologies Inc.) Long-Term Ambulatory Cardiac Rhythm Monitoring. Hayes, Inc.; February 2019.
40. Hindricks G, Pokushalov E, Urban L, Taborisky M, Kuck KH, Lebedev D, et al. XPECT Trial Investigators. Performance of a new leadless implantable cardiac monitor in detecting and quantifying atrial fibrillation: Results of the XPECT trial. *Circ Arrhythm Electrophysiol*. 2010 Apr 1;3(2):141-7.
41. Hoefman E, Bindels PJ, van Weert HC. Efficacy of diagnostic tools for detecting cardiac arrhythmias: systematic literature search. *Neth Heart J*. 2010; 18(11):543-551.
42. Iglesias JF, Graf D, Forclaz A, Schlaepfer J, Fromer M, Pruvot E. Stepwise evaluation of unexplained syncope in a large ambulatory population. *Pacing Clin Electrophysiol*. 2009 Mar;32 Suppl 1:S202-6.
43. iRhythm Technologies ZIO^{XT}. Accessed August 25, 2021. Available at URL address: https://www.irhythmtech.com/zio_xt_precautions
44. Jacob S, Kommuri NV, Zalawadiya SK, Meissner MD, Lieberman RA. Sensing performance of a new wireless implantable loop recorder: a 12-month follow up study. *Pacing Clin Electrophysiol*. 2010 Jul;33(7):834-40.
45. January CT, Wann LS, Calkins H, Chen LY, Cigarroa JE, Cleveland JC, et al. 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. 2019 Jul 9;74(1):104-132.
46. Kadish AH, Reiffel JA, Clauser J, Prater S, Menard M, Kopelman H. Frequency of serious arrhythmias detected with ambulatory cardiac telemetry. *Am J Cardiol*. 2010 May 1;105(9):1313-6.
47. Kamel H, Navi BB, Eljovich L, Josephson SA, Yee AH, Fung G, et al. Pilot randomized trial of outpatient cardiac monitoring after cryptogenic stroke. *Stroke*. 2013 Feb;44(2):528-30.
48. Kapa, S, Epstein AE, Callans DJ, Garcia FC, Lin D, Bala R, et al. Assessing arrhythmia burden after catheter ablation of atrial fibrillation using an implantable loop recorder: the ABACUS study. *J Cardiovasc. Electrophysiol*. 2013 Aug;24(8):875-8.
49. Kaura A, Sztriha L, Chan FK, Aeron-Thomas J, Gall N, Piechowski-Jozwiak B, et al. Early prolonged ambulatory cardiac monitoring in stroke (EPACS): an open-label randomised controlled trial. *Eur J Med Res*. 2019 Jul 26;24(1):25.
50. Kirchhof P, Benussi S, Kotecha D, Ahlsson A, Atar D, Casadei B, et al. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS. *Eur J Cardiothorac Surg*. 2016 Nov;50(5):e1-e88.
51. Kishore A, Vail A, Majid A, Dawson J, Lees KR, Tyrrell PJ, Smith CJ. Detection of atrial fibrillation after ischemic stroke or transient ischemic attack: a systematic review and meta-analysis. *Stroke*. 2014 Feb;45(2):520-6.

52. Koh KT, Law WC, Zaw WM, Foo DHP, Tan CT, Steven A, et al. Smartphone electrocardiogram for detecting atrial fibrillation after a cerebral ischaemic event: a multicentre randomized controlled trial. *Europace*. 2021 Jul 18;23(7):1016-1023.
53. Krahn AD, Klein GJ, Yee R, Skanes AC. Randomized assessment of syncope trial – conventional diagnostic testing versus a prolonged monitoring system. *Circ* 2001;104(1):46-51.
54. Krahn A, Klein G, Yee R, Takle-Newhouse T, Norris C. Use of an extended monitoring strategy in patients with problematic syncope. *Circulation*. 1999;99:406-10.
55. Kusiak A, Jastrzębski M, Bednarski A, Kułakowski P, Piotrowski R, Koźluk E, et al. Diagnostic value of implantable loop recorder in patients undergoing cryoballoon ablation of atrial fibrillation. *Ann Noninvasive Electrocardiol*. 2020 Jul;25(4):e12733.
56. Kusumoto FM, Schoenfeld MH, Barrett C, Edgerton JR, Ellenbogen KA, Gold MR, et al. 2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients With Bradycardia and Cardiac Conduction Delay: Executive Summary. *Circulation*. 2018 Nov 6:CIR0000000000000627.
57. Lee R, Mittal S. Utility and limitations of long-term monitoring of atrial fibrillation using an implantable loop recorder. *Heart Rhythm*. 2018 Feb;15(2):287-295.
58. Madias C. Ambulatory ECG monitoring. In: UpToDate, Zimetbaum PJ, Yeon SB (Eds). UpToDate, Waltham, MA. Literature review current through: July 2021. Topic last updated: August 20, 2020. Accessed August 25, 2021
59. Maggi R, Rafanelli M, Ceccofiglio A, Solari D, Brignole M, Ungar A. Additional diagnostic value of implantable loop recorder in patients with initial diagnosis of real or apparent transient loss of consciousness of uncertain origin. *Europace*. 2014 Aug;16(8):1226-30.
60. Mamchur SE, Khomenko EA, Chichkova TY, Romanova MP, Evtushenko VV, Polikutina OM. Noninvasive long-term ECG monitoring vs. loop recorder implantation for the atrial fibrillation management. *Ann Noninvasive Electrocardiol*. 2020 Mar;25(2):e12675.
61. Medtronic. Reveal® Insertable Cardiac Monitor (ICM). © 2021 Medtronic. Accessed August 25, 2021. Available at URL address: <https://www.medtronic.com/us-en/healthcare-professionals/products/cardiac-rhythm/cardiac-monitors.html>
62. Miller DJ, Khan MA, Schultz LR, Simpson JR, Katramados AM, Russman AN, Mitsias PD. Outpatient cardiac telemetry detects a high rate of atrial fibrillation in cryptogenic stroke. *J Neurol Sci*. 2013 Jan 15;324(1-2):57-61. doi: 10.1016/j.jns.2012.10.001.
63. Mitchell B. Overview of Arrhythmias. The Merck Manual Online. January 2021. August 25, 2021. Available at URL <https://www.merckmanuals.com/professional/cardiovascular-disorders/arrhythmias-and-conduction-disorders/overview-of-arrhythmias?query=overview%20of%20arrhythmias>
64. Mittal S, Movsowitz C, Steinberg JS. Ambulatory external electrocardiographic monitoring: focus on atrial fibrillation. *J Am Coll Cardiol*. 2011 Oct 18;58(17):1741-9.
65. Musat DL, Milstein N, Mittal S. Implantable Loop Recorders for Cryptogenic Stroke (Plus Real-World Atrial Fibrillation Detection Rate with Implantable Loop Recorders). *Card Electrophysiol Clin*. 2018 Mar;10(1):111-118.
66. National Institute for Health and Care Excellence (NICE). Atrial fibrillation: diagnosis and management. NICE guideline [NG196]. April 2021. Accessed September 7, 2021. Available at URL <https://www.nice.org.uk/guidance/ng196>

67. National Institute for Health and Care Excellence (NICE). Implantable cardiac monitors to detect atrial fibrillation after cryptogenic stroke. DG41. September 2020; updated June 2021. Accessed August 26, 2021. Available at URL <https://www.nice.org.uk/guidance/DG41>
68. National Institute for Health and Care Excellence (NICE). KardiaMobile for the ambulatory detection of atrial fibrillation. Medtech innovation briefing [MIB232]. October 2020a. September 7, 2021. Available at URL <https://www.nice.org.uk/advice/mib232>
69. National Institute for Health and Care Excellence (NICE). Lead-I ECG devices for detecting symptomatic atrial fibrillation using single time point testing in primary care. DG35. May 2019. August 25, 2021. Available at URL <https://www.nice.org.uk/guidance/dg35>
70. National Institute for Health and Care Excellence (NICE). Transient loss of consciousness ('blackouts') in over 16s. CG109. August 2010; updated September 2014. Accessed September 7, 2021. Available at URL <https://www.nice.org.uk/guidance/cg109>
71. National Institute for Health and Care Excellence (NICE). Zio XT for detecting cardiac arrhythmias. Medical technologies guidance 52. December 2020b. Accessed September 7, 2021. Available at URL <https://www.nice.org.uk/guidance/mtg52>
72. Olgin JE. Approach to the Patient with Suspected Arrhythmia. In: Goldman L, Schafer AI. Goldman-Cecil Medicine. 26th ed. Philadelphia, PA: Elsevier, Inc; 2020. Ch 56. pgs 318-326.e2
73. Padmanabhan D, Kancharla K, El-Harasis MA, Isath A, Makkar N, Noseworthy PA, Friedman PA, et al. Diagnostic and therapeutic value of implantable loop recorder: A tertiary care center experience. *Pacing Clin Electrophysiol*. 2019 Jan;42(1):38-45.
74. Passman R. Catheter ablation to prevent recurrent atrial fibrillation: Anticoagulation. In: UpToDate, Knight BP, Estes NA, Yeon SB (Eds). UpToDate, Waltham, MA. Literature review current through: July 2021. Topic last updated: October 15, 2019. Accessed August 25, 2021.
75. Passman R, Leong-Sit P, Andrei AC, Huskin A, Tomson TT, Bernstein R, et al. Targeted Anticoagulation for Atrial Fibrillation Guided by Continuous Rhythm Assessment With an Insertable Cardiac Monitor: The Rhythm Evaluation for Anticoagulation With Continuous Monitoring (REACT.COM) Pilot Study. *J Cardiovasc Electrophysiol*. 2016 Mar;27(3):264-70.
76. Pedersen CT, Kay GN, Kalman J, Borggrefe M, Della-Bella P, Dickfeld T, et al. EHRA/HRS/APHS expert consensus on ventricular arrhythmias. *Heart Rhythm*. 2014 Oct;11(10):e166-96.
77. Perez MV, Mahaffey KW, Hedlin H, Rumsfeld JS, Garcia A, Ferris T, et al. Large-Scale Assessment of a Smartwatch to Identify Atrial Fibrillation. *N Engl J Med*. 2019 Nov 14;381(20):1909-1917. Podoleanu C, DaCosta A, Defaye P, et al. Early use of an implantable loop recorder in syncope evaluation: a randomized study in the context of the French healthcare system (FRESH study). *Arch Cardiovasc Dis*. 2014; 107(10):546-552.
78. Pokushalov E, Romanov A, Corbucci G, Artyomenko S, Turov A, Shirokova N, et al. Use of an implantable monitor to detect arrhythmia recurrences and select patients for early repeat catheter ablation for atrial fibrillation: a pilot study. *Circ Arrhythm Electrophysiol*. 2011 Dec;4(6):823-31.
79. Reiffel JA, Schwarzberg R, Murry M. Comparison of autotriggered memory loop recorders versus standard loop recorders versus 24-hour holter monitors for arrhythmia detection. *Am J Cardiol*. 2005;95(9):1055-9.
80. Reiffel JA, Verma A, Kowey PR, Halperin JL, Gersh BJ, Wachter R, et al. Incidence of Previously Undiagnosed Atrial Fibrillation Using Insertable Cardiac Monitors in a High-Risk Population: The REVEAL AF Study. *JAMA Cardiol*. 2017 Oct 1;2(10):1120-1127.

81. Rho R, Vossler M, Blancher S, Poole JE. Comparison of 2 ambulatory patch ECG monitors: The benefit of the P-wave and signal clarity. *Am Heart J*. 2018 Sep;203:109-117.
82. Ringwala SM, Tomson TT, Passman RS. Cardiac Monitoring for Atrial Fibrillation in Cryptogenic Stroke. *Cardiol Clin*. 2016 May;34(2):287-97.
83. Ritter MA, Kochhauser S, Duning T, et al. Occult atrial fibrillation in cryptogenic stroke: detection by 7-day electrocardiogram versus implantable cardiac monitors. *Stroke*. 2013; 44(5):1449-1452.
84. Rosanio S, Schwarz ER, Ware DL, Vitarelli A. Syncope in adults: systematic review and proposal of a diagnostic and therapeutic algorithm. *Int J Cardiol*. 2013 Jan 20;162(3):149-57.
85. Rosenberg MA, Samuel M, Thosani A, Zimetbaum PJ. Use of a noninvasive continuous monitoring device in the management of atrial fibrillation: a pilot study. *Pacing Clin Electrophysiol*. 2013 Mar;36(3):328-33.
86. Sanna T, Diener HC, Passman RS, et al. Cryptogenic stroke and underlying atrial fibrillation. *N Engl J Med*. 2014; 370(26):2478-2486
87. Schreiber D, Sattar A, Drigalla D, Higgins S. Ambulatory cardiac monitoring for discharged emergency department patients with possible cardiac arrhythmias. *West J Emerg Med*. 2014 Mar;15(2):194-8.
88. Sheldon RS, Grubb BP, Olshansky B, Shen WK, Calkins H, Brignole M, et al. 2015 heart rhythm society expert consensus statement on the diagnosis and treatment of postural tachycardia syndrome, inappropriate sinus tachycardia, and vasovagal syncope. *Heart Rhythm*. 2015 Jun;12(6):e41-63.
89. Shen WK, Sheldon RS, Benditt DG, Cohen MI, Forman DE, Goldberger ZD, et al. 2017 ACC/AHA/HRS Guideline for the Evaluation and Management of Patients With Syncope: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *Circulation*. 2017 Aug 1;136(5):e25-e59.
90. Sivakumaran S, Krahn A, Finan J, Yee R, Renner S, Skanes A. A prospective randomized comparison of loop recorders versus Holter monitors in patients with syncope or presyncope. *Am J Med*. 2003;115(1):1-5.
91. Smith WM, Riddell F, Madon M, Gleva MJ. Comparison of diagnostic value using a small, single channel, P-wave centric sternal ECG monitoring patch with a standard 3-lead Holter system over 24 hours. *Am Heart J*. 2017 Mar;185:67-73.
92. Solbiati M, Casazza G, Dipaola F, Barbic F, Caldato M, Montano N, et al. The diagnostic yield of implantable loop recorders in unexplained syncope: A systematic review and meta-analysis. *Int J Cardiol*. 2017 Mar 15;231:170-176.
93. Solbiati M, Costantino G, Casazza G, Dipaola F, Galli A, Furlan R, et al. Implantable loop recorder versus conventional diagnostic workup for unexplained recurrent syncope. *Cochrane Database Syst Rev*. 2016 Apr 19;4:CD011637.
94. Sposato LA, Cipriano LE, Saposnik G, Ruiz Vargas E, Riccio PM, Hachinski V. Diagnosis of atrial fibrillation after stroke and transient ischaemic attack: a systematic review and meta-analysis. *Lancet Neurology* 2015;14(4):377-387.
95. Steinberg JS, Varma N, Cygankiewicz I, Aziz P, Balsam P, Baranchuk A, et al. 2017 ISHNE-HRS expert consensus statement on ambulatory ECG and external cardiac monitoring/telemetry. *Heart Rhythm* 2017;14(7):e55-e96.

96. Steinhubl SR, Waalen J, Edwards AM, Ariniello LM, Mehta RR, Ebner GS, et al. Effect of a Home-Based Wearable Continuous ECG Monitoring Patch on Detection of Undiagnosed Atrial Fibrillation: The mSToPS Randomized Clinical Trial. *JAMA*. 2018 Jul 10;320(2):146-155.
97. Sulke N, Sugihara C, Hong P, Patel N, Freemantle N. The benefit of a remotely monitored implantable loop recorder as a first line investigation in unexplained syncope: the EaSyAS II trial. *Europace*. 2016 Jun;18(6):912-8.
98. Tanno K. Use of implantable and external loop recorders in syncope with unknown causes. *J Arrhythm*. 2017 Dec;33(6):579-582
99. Thijs VN, Brachmann J, Morillo CA, Passman RS, Sanna T, Bernstein RA et al. Predictors for atrial fibrillation detection after cryptogenic stroke: results from CRYSTAL AF. *Neurology*. 2016;86(3):261-269.
100. Tung CE, Su D, Turakhia MP, Lansberg MG. Diagnostic Yield of Extended Cardiac Patch Monitoring in Patients with Stroke or TIA. *Front Neurol*. 2015 Jan 12;5:266
101. Turakhia MP, Hoang DD, Zimetbaum P, Miller JD, Froelicher VF, Kumar UN, et al. Diagnostic utility of a novel leadless arrhythmia monitoring device. *Am J Cardiol*. 2013 Aug 15;112(4):520-4.
102. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Searchable 510(k) database. Product Code: DSH. Accessed August 25, 2021. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnmn.cfm>
103. U.S. Food and Drug Administration (FDA). 510(k) Summary. Center for Devices and Radiologic Health (CDRH). K122356. Alivecor heart monitor for iphone. 2012 November. Accessed August 25, 2021. Available at URL address: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnmn.cfm?ID=K122356>
104. U.S. Food and Drug Administration (FDA). 510(k) summary. Center for Devices and Radiological Health (CDRH). K171514. BioMonitor 2 Insertable Cardiac Monitor. 2017 June. Accessed August 25, 2021. Available at URL address: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnmn.cfm?ID=K171514>
105. U.S. Food and Drug Administration (FDA). 510(k) summary. Center for Devices and Radiological Health (CDRH). K003707. CardioNet ambulatory ECG monitor. 2001 May. Accessed August 25, 2021. Available at URL address: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnmn.cfm?ID=K003707>
106. U.S. Food and Drug Administration (FDA). 510(k) summary. Center for Devices and Radiological Health (CDRH). K063222. CardioNet ambulatory ECG monitor with arrhythmia detection. 2006 November. Accessed August 26, 2021. Available at URL address: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnmn.cfm?ID=K063222>
107. U.S. Food and Drug Administration (FDA). 510(k) summary. Center for Devices and Radiological Health (CDRH). K012241 CardioNet ambulatory ECG monitor with arrhythmia detection. 2002 February. Accessed August 25, 2021. Available at URL address: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnmn.cfm?ID=K012241>
108. U.S. Food and Drug Administration (FDA). 510(k) summary. Center for Devices and Radiological Health (CDRH). K163407. Confirm Rx Insertable Cardiac Monitor (ICM) System. 2017 September. Accessed August 25, 2021. Available at URL address: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnmn.cfm?ID=K163407>
109. U.S. Food and Drug Administration (FDA). 510(k) summary. Center for Devices and Radiological Health (CDRH). K060911. CG-6108 ECG Monitoring System. 2006 August. Accessed August 25, 2021.

Available at URL address:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K060911>

110. U.S. Food and Drug Administration (FDA). 510(k) summary. Center for Devices and Radiological Health (CDRH). K170565. LifeWatch Mobile Cardiac Telemetry 3 Lead LifeWatch MCT 3L. 2017 August. Accessed August 25, 2021. Available at URL address:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K170565>
111. U.S. Food and Drug Administration (FDA). 510(k) summary. Center for Devices and Radiological Health (CDRH). K020825. King of Hearts Express + AF Monitor. 2002 April. Accessed August 25, 2021. Available at URL address:
<https://www.accessdata.fda.gov/SCRIPTS/cdrh/devicesatfda/index.cfm?db=pmn&id=K020825>
112. U.S. Food and Drug Administration (FDA). 510(k) summary. Center for Devices and Radiological Health (CDRH). K982803. HeartLink II. 1998 November. Accessed August 26, 2021. Available at URL address:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K982803>
113. U.S. Food and Drug Administration (FDA). 510(k) summary. Center for Devices and Radiological Health (CDRH). K133701. Nuvant™ Mobile Cardiac Telemetry System. 2014 February. Accessed August 25, 2021. Available at URL address:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K133701>
114. U.S. Food and Drug Administration (FDA). 510(k) summary. Center for Devices and Radiological Health (CDRH). K162855. Reveal LINQ. 2017 February. Accessed August 25, 2021. Available at URL address:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K162855>
115. U.S. Food and Drug Administration (FDA). 510(k) summary. Center for Devices and Radiological Health (CDRH). K103764. Reveal XT insertable cardiac monitor, model 9529 and Reveal DX insertable cardiac monitor, model 9528. 2011 May. Accessed August 25, 2021. Available at URL address:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K103764>
116. U.S. Food and Drug Administration (FDA). 510(k) summary. Center for Devices and Radiologic Health (CDRH). 510(k) K003667. Reveal® Plus Insertable Loop Recorder (ILR) System. 2001 February. Accessed August, 2021. Available at URL address:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K003667>
117. U.S. Food and Drug Administration (FDA). 510(k) summary. Center for Devices and Radiologic Health (CDRH). 510(k) K063035. Sleuth™ Implantable ECG Monitoring System. 2007 October. Accessed August 26, 2021. Available at URL address:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K063035>
118. U.S. Food and Drug Administration (FDA). 510(k) summary. Center for Devices and Radiological Health (CDRH). K040942. Vital Signs Recorder and Transmitter (VST™). 2004 September. Accessed August 26, 2021. Available at URL address:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K040942>
119. U.S. Food and Drug Administration (FDA). 510(k) summary. Center for Devices and Radiologic Health (CDRH). 510(k) K113862. Zio® Patch. 2012 February. Accessed August 26, 2021. Available at URL address: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K113862>
120. Wechselberger S, Kronborg M, Huo Y, Piorkowski J, Neudeck S, Päßler E, et al. Continuous monitoring after atrial fibrillation ablation: the LINQ AF study. *Europace*. 2018 Nov 1;20(FI_3):f312-f320.
121. Yenikomshian M, Jarvis J, Patton C, Yee C, Mortimer R, et al. Cardiac arrhythmia detection outcomes among patients monitored with the Zio patch system: a systematic literature review. *Curr Med Res Opin*. 2019 Oct;35(10):1659-1670.

122. Ziegler PD, Rogers JD, Ferreira SW, Nichols AJ, Richards M, Koehler JL, et al. Long-term detection of atrial fibrillation with insertable cardiac monitors in a real-world cryptogenic stroke population. *Int J Cardiol.* 2017 Oct 1;244:175-179.
123. Zuern CS, Kiliass A, Berlitz P, Seizer P, Gramlich M, Müller K, et al. Anticoagulation after catheter ablation of atrial fibrillation guided by implantable cardiac monitors. *Pacing Clin Electrophysiol.* 2015 Jun;38(6):688-93.

"Cigna Companies" refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Cigna Behavioral Health, Inc., Cigna Health Management, Inc., QualCare, Inc., and HMO or service company subsidiaries of Cigna Health Corporation. The Cigna name, logo, and other Cigna marks are owned by Cigna Intellectual Property, Inc. © 2021 Cigna.