MEDICAL COVERAGE POLICY	
SERVICE:	**Cardiac Monitoring - Outpatient**
Policy Number:	**065**
Effective Date:	**03/01/2021**
Last Review:	**01/28/2021**
Next Review Date:	**01/28/2022**

Important note
Unless otherwise indicated, this policy will apply to all lines of business.
Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage (EOC) or Summary Plan Description (SPD) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

SERVICE: Cardiac Monitoring - Outpatient (Mobile Outpatient Cardiac Monitoring and Ziopatch®)

PRIOR AUTHORIZATION: Not required.

POLICY:

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination) or LCD (Local Coverage Determination). If there is no applicable NCD or LCD, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid TMPPM.

SWHP/FIrstCare considers external intermittent cardiac event monitors (i.e., external loop recorders) medically necessary for **ANY** of the following conditions:

1. To document a dysrhythmia instead of using a Holter monitor or if a Holter monitor fails to document a suspected dysrhythmia; OR
2. To document the benefit after initiating drug therapy for a dysrhythmia; OR
3. To document the recurrence of a dysrhythmia after discontinuation of drug therapy; OR
4. To document the results after an ablation procedure for dysrhythmia; OR
5. To evaluate syncope, palpitations and lightheadedness that are thought to be secondary to a cardiac dysrythmia, AND all other methods have failed to illuminate the etiology.

External loop recorders are considered experimental and investigational for all other indications.

SWHP considers mobile cardiovascular telemetry (MCT) (e.g., Ziopatch®, CardioNet Mobile Cardiac Outpatient Telemetry (MCOT) Service; Cardiac Telecom and Health Monitoring Services of America's Telemetry @ Home Service, etc.) medically necessary for evaluation of recurrent unexplained episodes of pre-syncope, syncope, palpitations, or dizziness when **ALL** of the following criteria are met:

1. A cardiac dysrhythmia is suspected as the cause of the symptoms; **AND**
2. Members have a non-diagnostic Holter monitor, or symptoms occur infrequently (less frequently than daily) such that the dysrhythmia is unlikely to be diagnosed by short term monitoring; **AND**
3. All other methods have failed to illuminate the etiology.

Or for atrial fibrillation evaluation: Prolonged monitoring is required specifically to ensure the absence of atrial fibrillation prior to the discontinuation of anticoagulation therapy.

SWHP considers an implantable loop recorder (e.g., Reveal Insertable Loop Recorder by Medtronic, Inc.) medically necessary for evaluation of recurrent unexplained episodes of pre-syncope, syncope, palpitations, or dizziness when **ALL** of the following criteria are met:

1. A cardiac dysrhythmia is suspected as the cause of the symptoms; **AND**
2. Non-invasive ambulatory monitoring, consisting of either MCT or two 30-day external loop recordings, fails to establish a definitive diagnosis because the symptoms occur so infrequently and unpredictably that the monitoring period may not have been long enough to capture a diagnostic ECG; **AND**
3. All other methods have failed to illuminate the etiology.

Implantable loop recorders are considered experimental and investigational for all other indications.

SWHP/FirstCare considers the following experimental and investigational because their clinical value has not been established:

- Biotronik BioMonitor
- Kardia Mobile (previously known as AliveCore Mobile ECG, AliveCor Heart Monitor (iPhoneECG))
- Mobile patient management systems (e.g., BodyGuardian Remote Monitoring System, and iHEART)
- Self-monitoring ECG technologies or the ViSi Mobile Monitoring System
- CardioPatch

Invasive Congestive Heart Failure Monitoring:

SWHP considers implantable congestive heart failure monitors (e.g., the Chronicle IHM System, Cardiomems™ HF System, HeartPOD™ System, Promote® LAP System) experimental and investigational and unproven because such devices have not been shown to improve clinical outcomes compared to standard methods of heart failure monitoring.

Self-contained Pacemaker Monitors:

SWHP considers self-contained pacemaker monitors medically necessary for members with cardiac pacemakers. These include the following types:

1. Audible/visible signal pacemaker monitors -- these devices produce an audible and visible signal that indicates the pacemaker rate.
2. Digital electronic pacemaker monitors -- these devices provide the member with an instantaneous digital readout of his/her pacemaker pulse rate.

A specialized telephone attachment for trans-telephonic transmission of pacemaker monitoring results is also considered medically necessary. The Pace Trac is an example of a pacemaker monitor currently on the market.

Pulse Tachometers:

SWHP considers Pulse tachometers (pulse rate monitors, heart rate monitors) as not meeting SWHP's definition of covered durable medical equipment in that they are not primarily medical in nature and are normally of use in the absence of illness or injury. Examples of brand names of

pulse tachometers include the Exersentry, the Insta-Pulse, and the MacLevy Omni Pulse. These are not covered services.

Blood Pressure Monitors and Stethoscopes:

Home blood pressure monitors (sphygmomanometers, blood pressure cuffs) and stethoscopes do not meet SWHP's definition of covered durable medical equipment in that they may be of use in the absence of illness and injury. Following Medicare rules, SWHP covers blood pressure monitors and stethoscopes only for members receiving hemodialysis or peritoneal dialysis in the home.

SWHP considers automated oscillometer blood pressure (BP) monitors (e.g., Dinamap, Omron, and the BpTRU) for home use experimental and investigational because they have not been demonstrated to provide better health outcomes than conventional BP monitors (see overview).

OVERVIEW: Cardiac event monitors are small portable devices worn by a patient during normal activity for up to 30 days. The device has a recording system capable of storing several minutes of the individual's electrocardiogram (EKG) record. The patient can initiate EKG recording during a symptomatic period of dysrhythmia. These monitors are particularly useful in obtaining a record of dysrhythmia that would not be discovered on a routine EKG or a dysrhythmia that is so infrequent that it is not detected during a 24-hour period by a Holter monitor.

Mobile cardiovascular telemetry (MCT) refers to noninvasive ambulatory cardiac event monitors with extended memory capable of continuous measurement of heart rate and rhythm over several days, with transmission of results to a remote monitoring center. MCT is similar to standard cardiac telemetry used in the hospital setting.

A systematic evidence review of remote cardiac monitoring prepared for the Agency for Healthcare Research and Quality by the ECRI Evidence-based Practice Center (**AHRQ, 2007**) reached the following conclusions about the evidence for MCT: "This study [by Rothman, et al., 2007] was a high-quality multicenter study with few limitations. Therefore, the evidence is sufficient to conclude that real-time continuous attended monitoring leads to change in disease management in significantly more patients than do certain ELRs [external loop recorders]. However, because this is a single multicenter study, the strength of evidence supporting this conclusion is weak. Also, the conclusion may not be applicable to ELRs with automatic event activation, as this model was underrepresented in the RCT [by Rothman, et al., 2007] (only 16% of patients used this model)."

Congestive Heart Failure Telemonitoring:

Non-invasive telemonitoring for congestive heart failure involves the trans-telephonic transmission of weight, blood pressure (BP), heart rate and rhythm to a remote monitoring center. The Trans-European Network-Home-Care Management System (TEN-HMS) study is a randomized controlled clinical trial comparing home telemonitoring (HTM) to nurse telephone support (NTS) and usual care (UC) for patients with heart failure who are at high risk of hospitalization or death. The study found that patients assigned to HTM did not have significantly better outcomes than patients assigned to NTS or UC.

Heart failure guidelines from the National Institute for Clinical Excellence (2003) stated that "[m]ore complex remote monitoring (such as telemonitoring) of patients with heart failure is in its infancy, but shows promise for the future."

Invasive Congestive Heart Failure Monitoring:

Implantable hemodynamic monitoring devices (e.g. CardioMEMS™) have features that allow remote monitoring of hemodynamic data in patients with heart failure. The Chronicle Implantable Hemodynamic Monitor (IHM) is approximately the size of a pacemaker. The device consists of an implantable monitor and a transvenous lead carrying a pressure sensor. The pressure-sensing lead continuously measures intracardiac pressure, body temperature, physical activity, and heart rate. Battery life is approximately three years. The Chronicle IHM has an investigational device exemption in the United States, which allows use of the device in clinical trials.

The California Technology Assessment Forum (Ollendorf, 2015) completed a clinical comparative effectiveness review of the CardioMEMS HF System for CHF published in 2015. The review concluded that the current body of evidence was promising but inconclusive

The UK National Institute for Health and Care Excellence (NICE) issued an Interventional Procedures Guidance in August 2013 on Insertion and Use of Implantable Pulmonary Artery Pressure Monitors in Chronic Heart Failure. NICE concluded that safety and efficacy evidence was “limited in both quality and quantity,” and recommended that PA pressure implants for HF monitoring be used only with special arrangements for evidence development.

The Canadian Agency for Drugs and Technologies in Health's assessment on implantable hemodynamic monitoring (the Chronicle IHM System) (Ho, 2008) stated that preliminary evidence from observational studies suggested a potential for reducing hospitalizations with the use of right ventricle implantable hemodynamic monitoring (IHM). The assessment noted, however, although a multi-center, randomized controlled trial (COMPASS-HF) showed a reduction in hospitalizations in the IHM group, the results were not statistically significant and the U.S. Food and Drug Administration panel concluded the trial failed to meet its primary efficacy endpoint. The report stated that large randomized controlled trials are needed to demonstrate the clinical utility of IHM, particularly in terms of its impact on reducing hospitalization and improving patient outcomes.

Home Blood Pressure Monitoring (HBPM)

USPSTF recommends screening for hypertension in adults. USPSTF recommends use of home blood pressure monitoring for management of hypertension. Data from quality studies suggest that elevated blood pressure readings from HBPM were associated with increased cardiovascular outcomes. Per USPSTF, HBPM is also recommended to confirm hypertension when ambulatory blood pressure monitoring is not feasible.

Automated Oscillometer Blood Pressure Monitors:

Multiple clinical studies reveal weaknesses of these monitors in specific populations and are not supportive of widespread use, favoring more standardized blood pressure measurements by trained professionals.

MANDATES: There are no mandated benefits or regulatory requirements for SWHP to provide coverage for these services.

CODES:

Important note:

CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:	33282 implantation of cardiac event monitor 33284 removal of implantable cardiac event monitor 33285 Insertion, subcutaneous cardiac rhythm monitor, including programming 33286 Removal, subcutaneous cardiac rhythm monitor 93224 Ext recording up to 48h with interpretation 93225 Ext recording up to 48h 93226 Ext recording up to 48h with report 93227 Ext recording up to 48h with report and interpretation 93228 Ext remote cardiac telemetry up to 30 days 93229 Ext remote cardiac telemetry up to 30 days with interpretation 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 Ext cardiac event monitoring with report and interpretation 93270 Ext cardiac event monitoring 93271 Ext cardiac event monitoring with analysis 93272 Ext cardiac event monitoring with report and interpretation 93285: Programming device evaluation with iterative adjustment of the implantable device to test the function of the device and select optional permanent programmed values with analysis, review and report by a physician or other qualified health care professional, implantable loop recorder system 93291: Interrogation device evaluation with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter, implantable loop recorder system, including heart rhythm derived data analysis

	93298: Interrogation device evaluation(s), up to 30 days, implantable loop recorder system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional 93299: Interrogation device evaluation(s), up to 30 days, implantable cardiovascular monitor system or implantable loop recorder system, remote data acquisition(s), receipt of transmission(s) and technician review, technical support and distribution of results 0295T: External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage 0296T: External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; recording 0297T: External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; scanning analysis with report 0298T: External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; review and interpretation
CPT Not Covered:	33289 - Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring 93264 - Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days,
ICD10:	G45.9 - TIA I25.82 - Complete Coronary Occlusion I44.0 - I49.9 - Arrhythmias R00.0 - R00.9 - Tachy/brady R42 - Giddiness and dizziness R55 - Syncope and Collapse Z86.73 - Z86.74 - TIA/Sudden cardiac arrest, resuscitated
HCPCS NOT Covered:	C1764 implantable cardiac event recorder C2624 - Implantable wireless pulmonary artery pressure sensor E0616 implantable cardiac event monitor with memory, etc.

CMS: NCD 20.15 (NCD for Electrocardiographic Services; publication number 100-3)

LCD L36419 (6/8/17) Outpatient Wireless Pulmonary Artery Pressure Monitoring for Heart Failure:
"Given the information made available in the public domain, there appears to be limitations with lack of long-term clinical outcomes, specific study limitations, and need for additional studies. At this time, Novitas considers this device investigational and considers this non-covered unless in an approved clinical trial."

LCD L34953 Cardiac Event Detection Monitoring

LCD L34997 Real-Time, Outpatient Cardiac Telemetry

POLICY HISTORY:

Status	Date	Action
New	12/17/2010	New policy
Reviewed	12/6/2011	Reviewed.
Reviewed	11/15/2012	Reviewed. References updated.

Reviewed	10/24/2013	ICD10 added, LCD updated, Ziopatch® included
Reviewed	08/21/2014	Title change. LCD information appended.
Reviewed	08/11/2015	No changes
Reviewed	09/08/2016	
Reviewed	08/08/2017	Codes updated
Reviewed	01/16/2018	Minor updates. Reviewed Cardiomems™ status.
Reviewed	01/08/2019	No significant changes
Reviewed	01/23/2020	No significant changes
Reviewed	01/28/2021	Code list updated. Specific excluded devices listed.

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

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