

Policy Number:	065
Effective Date:	03/01/2025
Last Review:	02/10/2025
Next Review:	02/10/2026

Important note: Unless otherwise indicated, medical policies will apply to all lines of business. Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.

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

PRIOR AUTHORIZATION: Not required.

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for details.

Note: Unless otherwise indicated (see below), this policy will apply to all lines of business.

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination) or LCD (Local Coverage Determination). <u>NCD 20.15 Electrocardiographic Services</u>, <u>NCD 20.19</u> <u>Ambulatory Blood Pressure Monitoring</u>, and <u>L39490 Ambulatory Electrocardiograph (AECG)</u> <u>Monitoring</u>. Medicare NCD or LCD specific InterQual criteria may be used when available. If there are no applicable NCD or LCD criteria, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the <u>Texas Medicaid Provider Procedures</u> <u>Manual | TMHP</u> (TMPPM). If there are no applicable criteria to guide medical necessity decision making in the TMPPM, use the criteria set forth below.

BSWHP may consider external intermittent cardiac event monitors (i.e., external loop recorders) medically necessary for ANY of the following conditions:

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

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

BSWHP may consider 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 the evaluation of:

A. Atrial fibrillation when prolonged monitoring is required specifically to ensure the absence of atrial



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fibrillation prior to the discontinuation of anticoagulation therapy

- B. 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.

BSWHP may consider 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:'

- A. A cardiac dysrhythmia is suspected as the cause of the symptoms; AND
- B. 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**
- C. All other methods have failed to illuminate the etiology.

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

BSWHP considers the following experimental and investigational because their clinical value has not been established:

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

BSWHP may consider the CardioMEMS[™] Implantable congestive heart failure monitor medically necessary when the following criteria are met:

- A. Diagnosis of New York Heart Association (NYHA) III heart failure (HF) symptoms persistent despite maximally tolerated medical and device therapies; **AND**
- B. At least one HF related hospitalization within the previous 12 months; AND
- C. Able to take dual antiplatelet or anticoagulants for one-month post-implant; AND
- D. Greater than or equal to 18 years of age; AND
- E. Member has diagnosis of HF for at least three months, with either preserved or reduced left ventricular ejection fraction; AND
- F. PA branch diameter sized between 7 and 15 mm (this is the measurement range for deployment of the device and is generally not reported in imaging studies prior to the procedure); **AND**
- G. Body mass index (BMI) of ≤ 35; or if BMI > 35, a measurement of chest circumference at axillary level is required. If the chest circumference is greater than 165 cm, the sensor should not be implanted due to poor signal strength.



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H. Monitoring must occur at least once weekly.

BSWHP considers all other implantable congestive heart failure monitors (e.g., the Chronicle IHM System, HF System, HeartPODTM 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.

BSWHP may consider self-contained pacemaker monitors medically necessary for members with cardiac pacemakers. These include the following types:

- A. Audible/visible signal pacemaker monitors -- these devices produce an audible and visible signal that indicates the pacemaker rate.
- B. 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.

BSWHP does not cover Pulse tachometers (pulse rate monitors, heart rate monitors) as they do not meet BSWHP'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.

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, BSWHP covers blood pressure monitors and stethoscopes only for members receiving hemodialysis or peritoneal dialysis in the home.

BSWHP 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 BACKGROUND section).

BACKGROUND:

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.



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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:

The CardioMEMS implantable hemodynamic monitor (CM-IHM) system utilizes an implantable pulmonary artery pressure (PAP) sensor to allow patients to measure PAP remotely from home. Since elevated PAP is often an early indication of an impending HF exacerbation, data from CM-IHM can alert the patient and physician so that decisions regarding treatment can be made. Patients are instructed to obtain daily PAP readings, which are automatically uploaded to a database that can be accessed by the patient and caregivers. Physicians incorporate the PAP data into the HF treatment plan, often resulting in data-based dose changes to guideline-directed medical therapy.

In a meta-analysis evaluating CardioMEMS implantable hemodynamic monitor for management of HF (Thakker et al. (2021)), the authors concluded that pts with CM-IHM had reduced likelihood of hospitalizations compared with pts without CM-IHM. The authors also concluded that remote PAP monitoring is even more valuable during a pandemic like COVID-19.

National Institute for Health and Care Excellence (NICE) released a 2021 interventional procedures guidance evaluating the safety and efficacy of percutaneously implanted PAP sensors for monitoring heart failure (HF). Based on data from 9 studies, the NICE found that the evidence base is adequate to support the use of percutaneously implanted PAP sensors for managing chronic HF



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European Society of Cardiology (ESC) published in 2021 a guideline focused on making evidencebased recommendations specific to the diagnosis and treatment of HF. The ESC working group determined that PAP monitoring with a wireless system (e.g., CM-IHM) may be considered to improve clinical outcomes in patients with symptomatic HF (strength, IIb; level of evidence, B) (McDonagh et al., 2021).

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: None

CODES:

Important note: 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	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,33282 implantation of 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)



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	 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
	93297 - Interrogation device evaluation(s), (remote) up to 30 days, implantable
	cardiovascular physiologic monitor system, including analysis of 1 or more
	recorded physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health
	care professional
	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
CPT Not Covered	
ICD-10 Codes	G45.9 - TIA
	I25.82 - Complete Coronary Occlusion
	144.0 - 149.9 - 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 Codes	C1764 Implantable cardiac event recorder
	E0616 Implantable cardiac event monitor with memory, etc. C2624 Implantable wireless pulmonary artery pressure sensor
	02027 implantable wilcless pullionaly altely plessure sensor



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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 CardiomemsTM 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.
Reviewed	01/27/2022	Updated codes.
Reviewed	01/26/2023	Updated codes. Added reference to TAC regarding CardioMEMS
Updated	02/23/2023	Added criteria for CardioMEMS device
Reviewed	02/12/2024	Removed retired CPT codes (33284, 93299), added CPT code (93297). Formatting changes and added hyperlinks to CMS and TMPPM resources, beginning and ending note sections updated to align with CMS requirements and business entity changes. Removed retired LCDs.
Reviewed	02/10/2025	Removed duplicate CPT codes, formatting changes, updated ending note sections to align with business entity changes.

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP 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 BSWHP 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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Note:

Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plan.

RightCare STAR Medicaid is offered through Scott and White Health Plan in the Central Texas Medicaid Rural Service Area (MRSA); FirstCare STAR is offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs; and FirstCare CHIP is offered through FirstCare in the Lubbock Service Area.