Corporate Medical Policy

Cardiac Monitoring Devices in the Outpatient Setting

File Name: cardiac_monitoring_devices_in_the_outpatient_setting
Origination: 9/2010
Last Review: 10/2023

Description of Procedure or Service

A variety of outpatient cardiac monitoring devices are available to prompt a patient to seek medical help for prevention or early intervention of an impending or ongoing cardiac event. Examples include hemodynamic monitors to decrease episodes of acute decompensation in patients with heart failure by detecting physiologic changes that precede clinical symptoms, and cardiac ischemia monitors to detect electrocardiogram changes to alert the patient of a potential ongoing acute coronary event.

Cardiac Hemodynamic Monitors for Heart Failure
Patients with chronic heart failure are at risk of developing acute decompensated heart failure, often requiring hospital admission. Patients with a history of acute decompensation have additional risk of future episodes of decompensation and death. Reasons for the transition from a stable, chronic state to an acute, decompensated state include disease progression, as well as acute coronary ischemic events and dysrhythmias. While precipitating factors are frequently not identified, the most common preventable cause is noncompliance with medication and dietary regimens.

Strategies for reducing decompensation, and thus the need for hospitalization, are aimed at early identification of patients at risk for imminent decompensation. Programs for early identification of heart failure are characterized by frequent contact with patients to review signs and symptoms with a healthcare provider, and with education or adjustment of medications as appropriate. These encounters may occur face-to-face in the office or at home, or via transmission of symptoms and conventional vital signs, including weight, via cellular or computed technology.

Precise measurement of cardiac hemodynamics is often employed in the intensive care setting to carefully manage fluid status in acutely decompensated heart failure. Transthoracic echocardiography, transesophageal echocardiography (TEE), and Doppler ultrasound are noninvasive methods for monitoring cardiac output on an intermittent basis for the more stable patient, but are not addressed in this policy. A variety of biomarkers and radiologic techniques may be utilized for dyspnea when the diagnosis of acute decompensated heart failure is uncertain.

The criterion standard for hemodynamic monitoring is pulmonary artery catheters and central venous pressure catheters. However, they are invasive and may be inaccurate and inconsistent in predicting fluid responsiveness. Several studies have demonstrated that catheters fail to improve outcomes in critically ill patients and may be associated with causing harm. To overcome these limitations, multiple techniques and devices have been developed that use complex imaging technology and computer algorithms to estimate fluid responsiveness, volume status, cardiac output and tissue perfusion. Many of these are intended for use in the outpatient setting but have the potential also to be used in the emergency department, intensive care unit, and operating room. Four methods are reviewed in this policy: implantable pressure monitoring devices, thoracic bioimpedance, inert gas rebreathing, and arterial waveform during the Valsalva maneuver. The use of the last 3 is not widespread because of limitations including use of proprietary technology, making it difficult to confirm validity and lack of large RCTs to evaluate treatment decisions guided by these hemodynamic monitors.

Regulatory Status

Noninvasive Left Ventricular End-Diastolic Pressure (LVEDP) Measurement Devices

In 2004, the VeriCor® (CVP Diagnostics), a noninvasive LVEDP measurement device, was cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for the following indication:

"The VeriCor is indicated for use in estimating non-invasively, left ventricular end-diastolic pressure (LVEDP). This estimate, when used along with clinical signs and symptoms and other patient test results, including weights on a daily basis, can aid the clinician in the selection of further diagnostic tests in the process of reaching a diagnosis and formulating a therapeutic plan when abnormalities of intravascular volume are suspected. The device has been clinically validated in males only. Use of the device in females has not been investigated."

Thoracic Bioimpedance Devices

Multiple thoracic impedance measurement devices that do not require invasive placement have been cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices used for peripheral blood flow monitoring.

Table 1 includes a representative list of noninvasive thoracic impedance plethysmography devices, but is not meant to be comprehensive.

Table 1: Non-Invasive Thoracic Impedance Plethysmography Devices

Device	Manufacturer	FDA Clearance
BioZ ® Thoracic Impedance Plethysmograph	SonoSite WA)	2009
Zoe® Fluid Status Monitor	Noninvasive Medical Technologies	2004
Cheetah Starling SV	Cheetah Medical	2008
PhysioFlow® Signal Morphology-based Impedance Cardiography (SM-ICG™)	Vasocom, now NeuMeDx,	2008
ReDS™ Wearable System	Sensible Medical Innovations	2015
Bodyport Cardiac Scale	Bodyport Inc.	2022

Also, several manufacturers market thoracic impedance measurement devices integrated into implantable cardiac pacemakers, cardioverter defibrillator devices, and cardiac resynchronization therapy devices. Thoracic bioimpedance devices integrated into implantable cardiac devices are not addressed in this policy.

Inert Gas Rebreathing

In 2006, the Innocor® (Innovision), an inert gas rebreathing device, was cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing inert gas rebreathing devices for use in computing blood flow.

Implantable Pulmonary Artery Pressure Sensor Devices

In 2014, the FDA approved the CardioMEMS™ Champion Heart Failure Monitoring System (CardioMEMS, now Abbott) through the premarket approval (PMA) process. This device consists of an implantable pulmonary artery (PA) sensor, which is implanted in the distal PA, a transvenous delivery system, and an electronic sensor that processes signals from the implantable PA sensor and transmits PA pressure measurements to a secure database. The device originally underwent FDA review in 2011, at which point the FDA found no reasonable assurance that the discussed monitoring system would be effective, particularly in certain subpopulations, although the FDA agreed that this monitoring system was safe for use in the indicated patient population. In 2022, the CardioMEMS™ HF Monitoring System received expanded approval for the treatment of New York Heart Association (NYHA) Class II-III patients who had been hospitalized at least 1 time in the prior year and/or had elevated natriuretic peptides.

Several additional devices that monitor cardiac output by measuring pressure changes in the PA or right ventricular outflow tract have been investigated in the research setting, but have not received FDA approval. These include the Chronicle® implantable continuous hemodynamic monitoring device (Medtronic), which includes a sensor implanted in the right ventricular outflow tract, the ImPressure® device (Remon Medical Technologies), which includes a sensor implanted in the PA, and the Cordella™ PA Pressure Sensor System (Endotronix, Inc.), which includes a sensor implanted in the PA.

Left Atrial Hemodynamic Monitor

This is an implantable device capable of detecting increases in LAP (left atrial pressure) before clinical deterioration. Direct monitoring of LAP may allow for earlier identification of incipient decompensation prior to clinical symptoms and could make it possible to guide the adjustment of vasodilator and diuretic dosing at an earlier stage.

The HeartPOD™ System (Savacor, Inc.) is a medical device that allows the patient to directly monitor left atrial pressure, the intracardiac electrogram, and core body temperature. The implant's readings are communicated with a hand-held computer called a Patient Advisory Module, or PAM. This information is used to adjust medications on a dose-by-dose basis according to the patient's prescriptive instructions. This permits real-time adjustment and dosing of medications similar to the way diabetics adjust insulin doses in response to home glucose monitoring. The HeartPOD™ System is not FDA approved at this time and is not available for commercial use in the U.S.

Intracardiac Ischemia Monitor

The AngelMed Guardian ® System, also known as the acute coronary syndrome event detector, is a cardiac monitor using an implantable intracardiac (right ventricular apex) lead that has the potential to detect rapid ST segment changes alerting the patient to an impending acute coronary occlusion. There are three components of the Guardian System, the first is the implantable medical device (IMD) which monitors the electrical activity (electrogram) of the heart and provides vibrations if changes are detected which sends an alert to the second component. The second component is the external device (EXD) which sets off lights and alarms when the alerts from the IMD are received, indicating the patient may need to seek medical attention. The third component is the programmer which collects and stores the data from the IMD.

The device records cardiac data and detects impending ischemic events through the use of a vibrational waning producing an alarm prior to symptom onset. The device is intended to be used in individuals who are considered at high-risk for ischemic cardiac events, including those with previous acute coronary events or previous myocardial infarctions, and diabetes, renal insufficiency, or increased thrombolysis in MI (TIMI) score. The use of this device is proposed to reduce the time from onset of an ischemic event to presentation in an emergency room, with potential clinical benefits of more efficient emergent care.

In April 2018, the AngelMed Guardian® System (Angel Medical Systems, Shrewsbury, NJ) was approved through the FDA premarket approval (PMA) process. The Guardian System is indicated as an adjunct to patient recognized symptoms. The device detects potential ongoing ACS events, characterized by sustained ST segment changes, and alerts the patient to seek medical attention for those potential ACS events.

Note: This policy only addresses use of these techniques in ambulatory care and outpatient settings.

Related Policies
Implantable Cardioverter Defibrillator

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.*

Policy

Cardiac monitoring devices in the outpatient setting are considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Cardiac Monitoring Devices in the Outpatient Setting are covered

Not applicable.

When Cardiac Monitoring Devices in the Outpatient Setting are not covered

In the ambulatory care and outpatient setting, cardiac hemodynamic monitoring for the management of heart failure utilizing thoracic bioimpedance, inert gas rebreathing, arterial pressure/Valsalva, implantable direct pressure monitoring of the pulmonary artery, and left atrial hemodynamic monitoring is considered investigational.

Intracardiac ischemia monitoring (i.e., AngelMed® Guardian System) is considered investigational for all indications including, but not limited to, detection of acute myocardial ischemic events.

Policy Guidelines

Cardiac Hemodynamic Monitors for Heart Failure

For individuals with New York Heart Association (NYHA) class II-IV heart failure in outpatient settings who have had a hospitalization in the past year and/or have elevated natriuretic peptides who receive hemodynamic monitoring with an implantable pulmonary artery pressure sensor device, the evidence includes randomized controlled trials (RCTs) and nonrandomized studies. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. One implantable pressure monitor, the CardioMEMS device, has U.S. Food and drug Administration (FDA) approval. The pivotal CHAMPION RCT reported a statistically significant 28% decrease in heart failure hospitalization (HFH) in patients implanted with the CardioMEMS device compared with usual care. However, trial results were potentially biased in favor of the treatment group due to the use of additional nurse communication to enhance protocol compliance with the device. The manufacturer conducted multiple analyses to address potential bias from the nurse interventions. Results were reviewed

favorably by the FDA. While these analyses demonstrated the consistency of benefit of the CardioMEMS device, all such analyses have methodologic limitations. Early safety data have been suggestive of a higher rate of procedural complications, particularly related to pulmonary artery injury. While the U.S. CardioMEMS post-approval study and CardioMEMS European Monitoring Study for Heart Failure (MEMS-HF) study reported a significant decrease in HFH with few device- or system-related complications at 1 year, the impact of nursing interventions remains unclear. The subsequent GUIDE-HF RCT failed to meet its primary efficacy endpoint, the composite of HFH, urgent heart failure visits, and death at 1 year. With the approval of the FDA, the statistical analysis plan was updated to pre-specify sensitivity analyses to assess the impact of COVID-19 on the trial. For the 72% of patients who completed follow-up prior to the public health emergency declaration in March 2020, a statistically significant 19% reduction in the primary endpoint was reported, driven by a 28% reduction in HFH. However, lifestyle changes during the COVID-19 pandemic such as changes in physical activity, exposure to infections, willingness to seek medical care, and adherence to medications are unmeasured and add imprecision to treatment effect estimates, as do alterations in provider behaviors. Enrollment of NYHA Class II patients was significantly enriched in the first 500 patients, potentially impacting the pre-COVID-19 analysis. Overall, the beneficial effect of CardioMEMS, if any, appears to be on the hospitalization outcome of the composite. Both urgent heart failure visits and death outcomes had hazard ratios favoring the control group with wide confidence intervals including the null value in pre-COVID-19, during-COVID-19, and overall analyses of the GUIDE-HF trial. No significant differences were observed in secondary quality of life and functional status outcomes. While the HFH reduction of 28% found in the pre-COVID-19 analysis is consistent with findings from the CHAMPION trial, it is unclear whether physician knowledge of treatment assignment biases the decision to hospitalize and administer intravenous diuretics. Given that the intervention is invasive and intended to be used for a highly prevalent condition and, in light of the absence of a demonstrated benefit on mortality and functional outcomes, the lack of periprocedural safety data, and unclear impact of COVID-19 on remote monitoring in the GUIDE-HF trial, the net benefit of the CardioMEMS device remains uncertain. Concerns may be clarified by the ongoing open access phase of the GUIDE-HF RCT and the German non-industry-sponsored PASSPORT-HF trial. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have heart failure in the outpatient setting who receive hemodynamic monitoring with thoracic bioimpedance, inert gas rebreathing or arterial pressure during Valsalva, the evidence includes uncontrolled prospective studies and case series. Relevant outcomes include overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. There is a lack of RCT evidence to evaluate whether the use of these technologies improves health outcomes over standard active management of the heart failure patient. The case series report physiologic measurement-related outcomes and the association between monitoring information and heart failure exacerbations, but do not provide definitive evidence on the efficacy of these devices. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Intracardiac Ischemia Monitor

The ALERTS trial was conducted to determine the safety and efficacy of the AngelMed Guardian system. The trial was a prospective, randomized multicenter study that used a Bayesian adaptive design to analyze sample size of patients based on interim treatment effect. Patients were selected based on high-risk status with a prior history of coronary artery disease, with 97% having had previous revascularization. A total of 910 patients were implanted with the Guardian device, with 451 in the treatment arm (device on) and 456 in the control arm in which the device was deactivated. After the 6 month randomized period, the alarms in all devices were activated. The primary endpoints of the study were the proportion of patients free from system-related complications and a composite effectiveness endpoint of late arrival (>2 hours) after a confirmed occlusive event, new Q-wave, and cardiac or unexplained death. The primary safety endpoint was met with a 96.7% event-free rate. The primary effectiveness endpoint was not met. The posterior probability of event reduction didn't meet the threshold for statistical significance and multiple study conduct issues

were observed, especially with respect to the time-to-door and the new Q wave MI endpoints. The quality of the electrocardiogram data and the inconsistency of the Q wave results caused early termination of the trial.

FDA approval of the device was granted after the FDA analyzed additional clinical events from the ALERTS trial that occurred during the randomized and nonrandomized periods. The analysis is known as ALERTS-ED, and included all emergency department (ED) visits outside of the initial randomization period. The ALERTS-ED analysis showed that the positive predictive value among patients who went to the ED based on the device was higher than in symptomatic patients without alarm-based monitoring. The false positive rate was 0.68 per person per year among those patients who relied on symptoms alone compared with 0.16 per person per year among those with the alarm on.

Additional studies are needed to assess the diagnostic accuracy of the Guardian System for intracardiac ischemia monitoring.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: *33289, 93264, 93701, 93799, 0525T, 0526T, 0527T, 0528T, 0529T, 0530T, 0531T, 0532T, C1833, C2624*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

2009American College of Cardiology Foundation/American Heart Association (ACCF/AHA). Focused Update: ACCF/AHA Guidelines for the Diagnosis and Management of Heart Failure in Adults. A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. (March 2009). Retrieved on August 25, 2010 from http://circ.ahajournals.org/cgi/reprint/CIRCULATIONAHA.109.192064v1.pdf

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.24, 7/8/10

Senior Medical Director – 9/2010

Adamson PB, Abraham WT, Aaron M et al. CHAMPION trial rationale and design: the long-term safety and clinical efficacy of a wireless pulmonary artery pressure monitoring system. J Card Fail 2011; 17(1):3-10.

National Institutes of Health (NIH). Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy (LAPTOP-HF). Clinical Trial #NCT01121107. Retrieved on August 15, 2011 from http://clinicaltrials.gov/ct2/show/NCT01121107?term=NCT01121107&rank=1

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.24, 7/14/11

Specialty Matched Consultant Advisory Panel review 10/2011

Medical Director review 12/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.24, 7/12/12

Specialty Matched Consultant Advisory Panel review 10/2012

Adamson PB, Gold MR, Bennett T et al. Continuous hemodynamic monitoring in patients with mild to moderate heart failure: results of The Reducing Decompensation Events Utilizing Intracardiac Pressures in Patients With Chronic Heart Failure (REDUCEhf) trial. Congest Heart Fail 2011; 17(5):248-54.

Yancy CW, Jessup M, Bozkurt B et al. 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.24, 7/11/13

Specialty Matched Consultant Advisory Panel review 10/2013

Food and Drug Administration (FDA). Summary of Safety and Effectiveness Data (SSED) -- CardioMEMS HF System. 2014. http://www.accessdata.fda.gov/cdrh_docs/pdf10/P100045b.pdf.

Loh JP, Barbash IM, Waksman R. Overview of the 2011 Food and Drug Administration Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting on the CardioMEMS Champion Heart Failure Monitoring System. J Am Coll Cardiol 2013; 61(15):1571-6.

Kamath SA, Drazner MH, Tasissa G et al. Correlation of impedance cardiography with invasive hemodynamic measurements in patients with advanced heart failure: the BioImpedance CardioGraphy (BIG) substudy of the Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness (ESCAPE) Trial. Am Heart J 2009; 158(2):217-23. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2720805/

Conraads VM, Tavazzi L, Santini M et al. Sensitivity and positive predictive value of implantable intrathoracic impedance monitoring as a predictor of heart failure hospitalizations: the SENSE-HF trial. Eur Heart J 2011; 32(18):2266-73.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.24, 7/10/14

Medical Director review 8/2014

Specialty Matched Consultant Advisory Panel review 11/2014

Senior Medical Director review 11/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.24, 7/9/15

Specialty Matched Consultant Advisory Panel review 10/2015

Medical Director review 10/2015

Medical Director review 5/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.24, 5/2016

Specialty Matched Consultant Advisory Panel review 10/2016

Medical Director review 10/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.24, 5/2017

Medical Director review 5/2017

Specialty Matched Consultant Advisory Panel review 10/2017

Medical Director review 10/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.24, 5/2018

Specialty Matched Consultant Advisory Panel review 10/2018

Medical Director review 10/2018

National Institutes of Health (NIH). AngelMed for Early Recognition and Treatment of STEMI (ALERTS). Clinical Trial #NCT00781118. https://clinicaltrials.gov/ct2/show/NCT00781118

Food and Drug Administration: AngelMed Guardian System PMA Approval April, 2018: https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150009A.pdf

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.24, 6/2019

Specialty Matched Consultant Advisory Panel review 10/2019

Medical Director review 10/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.24, 6/2020

Specialty Matched Consultant Advisory Panel review 10/2020

Medical Director review 10/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.24, 6/2021

Shavelle DM, Desai AS, Abraham WT, et al. Lower Rates of Heart Failure and All-Cause Hospitalizations During Pulmonary Artery Pressure-Guided Therapy for Ambulatory Heart Failure: One-Year Outcomes From the CardioMEMS Post-Approval Study. Circ Heart Fail. Aug 2020; 13(8): e006863.

Specialty Matched Consultant Advisory Panel review 10/2021

Medical Director review 10/2021

Specialty Matched Consultant Advisory Panel review 10/2022

Medical Director review 10/2022

Opasich C, Rapezzi C, Lucci D, et al. Precipitating factors and decision-making processes of short-term worsening heart failure despite "optimal" treatment (from the IN-CHF Registry). Am J Cardiol. Aug 15 2001; 88(4): 382-7. PMID 11545758

McAlister FA, Stewart S, Ferrua S, et al. Multidisciplinary strategies for the management of heart failure patients at high risk for admission: a systematic review of randomized trials. J Am Coll Cardiol. Aug 18 2004; 44(4): 810-9. PMID 15312864

Lindenfeld J, Zile MR, Desai AS, et al. Haemodynamic-guided management of heart failure (GUIDE-HF): a randomised controlled trial. Lancet. Sep 11 2021; 398(10304): 991-1001. PMID 34461042

Zile MR, Desai AS, Costanzo MR, et al. The GUIDE-HF trial of pulmonary artery pressure monitoring inheart failure: impact of the COVID-19 pandemic. Eur Heart J. Jul 14 2022; 43(27): 2603-2618. PMID35266003

Assmus B, Angermann CE, Alkhlout B, et al. Effects of remote haemodynamic-guided heart failuremanagement in patients with different subtypes of pulmonary hypertension: insights from the MEMS-HFstudy. Eur J Heart Fail. Dec 2022; 24(12): 2320-2330. PMID 36054647

Abraham WT, Stevenson LW, Bourge RC, et al. Sustained efficacy of pulmonary artery pressure toguide adjustment of chronic heart failure therapy: complete follow-up results from the CHAMPION randomized trial. Lancet. Jan 30 2016; 387(10017): 453-61. PMID 26560249

Angermann CE, Assmus B, Anker SD, et al. Pulmonary artery pressure-guided therapy in ambulatorypatients with symptomatic heart failure: the CardioMEMS European Monitoring Study for Heart Failure(MEMS-HF). Eur J Heart Fail. Oct 2020; 22(10): 1891-1901. PMID 32592227

Specialty Matched Consultant Advisory Panel review 10/2023

Medical Director review 10/2023

Policy Implementation/Update Information

9/28/10	New policy implemented as a combination of policies titled, "Non-Invasive Left Ventricular End Diastolic Pressure" and "Non-Invasive Measurements of Cardiac Hemodynamics in the Outpatient Setting". Cardiac hemodynamic monitoring in the outpatient setting is considered investigational. Reviewed by Senior Medical Director 9/2010. Notice given 9/28/10 Effective date 1/4/11.
1/4/11	Removed codes 0104T and 0105T. (mco)
8/30/11	Removed information regarding the Endosure® (CardioMEMS, Atlanta) wireless abdominal aortic aneurysm (AAA) pressure measurement device as this device is addressed in the policies titled, "Endovascular Stent Grafts for Abdominal Aortic Aneurism" and "Endovascular Stent Grafts for Thoracic Aortic Aneurism." Policy Guidelines updated. References updated. No changes to policy statements. (mco)
11/8/11	Specialty Matched Consultant Advisory Panel review 10/2011. No changes to Policy Statements. (mco)
12/30/11	Added new codes to "Billing/Coding" section: 0293T and 0294T. Effective date 1/1/2012. Added information on Left Atrial Hemodynamic Monitor, HeartPOD™ System, to "Description" section. Added "left atrial hemodynamic monitoring" to the "When not Covered" section. Medical Director review 12/2011. (mco)

9/4/12 References updated. Policy Guidelines updated. No changes to Policy Statements. (mco)

10/30/12 Specialty Matched Consultant Advisory Panel review 10/2012. No changes to Policy Statements. (mco)

8/27/13 Policy Guidelines updated. References updated. No changes to Policy Statements. (mco)

11/12/13 Specialty Matched Consultant Advisory Panel review 10/2013. No changes to Policy Statements. (mco)

8/26/14 Description section extensively revised to include new hemodynamic monitoring devices. References updated. Policy Guidelines updated. Medical Director review 8/2014. No changes to Policy Statement. Added C9741 (effective October 1, 2014) to Billing/Coding section. (mco)

12/30/14 References updated. Specialty Matched Consultant Advisory Panel review 11/2014. Senior Medical Director review. Added C2624 to the Billing/Coding section effective 1/1/15. No change to Policy statement. (td)

10/1/15 Policy Description section updated. Policy Guidelines section updated. References updated. Policy intent unchanged. References updated. (td)

12/30/15 Description section updated. References updated. Specialty Matched Consultant Advisory Panel review 10/29/2015. Medical Director review 10/2015.

7/1/16 Minor updates to the Description section. Policy Guidelines updated. References updated. Medical Director review 5/2016. (jd)

11/22/16 Specialty Matched Consultant Advisory Panel review 10/2016. Medical Director review 10/2016. (jd)

6/30/17 Description and Table 1 updated. References updated. Medical Director review 5/2017. (jd)

11/10/17 Minor revisions to Description section. Specialty Matched Consultant Advisory Panel review 10/2017. Medical Director review 10/2017. (jd)

12/29/17 Updated code section, deleting codes 0293T, 0294T effective 1/1/18, (jd)

6/8/18 Description section updated. Regulatory status revised. Policy guidelines and references updated. Medical Director review 5/2018. (jd)

For the policy titled: Cardiac Monitoring Devices in the Outpatient Setting

10/26/18 Title changed from Cardiac Hemodynamic Monitoring in the Outpatient Setting to Cardiac Monitoring Devices in the Outpatient Setting. Description section, regulatory status, and policy guidelines revised to include Intracardiac Ischemia Monitor, due to FDA approval of the AngelMed Guardian System. Policy statement updated to include when the AngelMed Guardian system is not covered: "Intracardiac ischemia monitoring (i.e., AngelMed® Guardian System) is considered investigational for all indications including, but not limited to, detection of acute myocardial ischemic events." Code section updated for codes effective 10/1/18 and 1/1/19. References updated. Specialty Matched Consultant Advisory Panel review 10/2018. Medical Director review 10/2018. (jd)

11/9/18 Minor date edits for clarification and consistency. (jd)

12/31/18	Billing/Coding section updated: adding 0525T, 0526T, 0527T, 0528T, 0529T, 0530T, 0531T, 0532T 33289, 93264 and deleting the codes, C9741, C9750 effective 1/1/19. (jd)
7/1/19	Description and Regulatory Status sections extensively reformatted; no change to policy intent. References updated. (jd)
10/29/19	Specialty Matched Consultant Advisory Panel review 10/2019. Medical Director review 10/2019. (jd)
11/10/20	Minor revisions to description section and regulatory status, no change to policy intent. Specialty Matched Consultant Advisory Panel review 10/2020. Medical Director review 10/2020. (jd)
11/2/21	Policy guidelines and references updated. Specialty Matched Consultant Advisory Panel review 10/20201. Medical Director review 10/2021. (jd)
12/30/21	The following code was added to the Billing/Coding section: C1833 effective 1/1/22. (jd)
11/1/22	Description, Regulatory Status and References updated. No change to policy statement. Specialty Matched Consultant Advisory Panel review 10/2022. Medical Director review 10/2022. (tm)
11/7/23	Description, Regulatory Status, Policy Guidelines and References updated. No change to policy statement. Specialty Matched Consultant Advisory Panel review 10/2023. Medical Director review 10/2023. (tm)