Clinical Policy Bulletin:
Cardiovascular Monitoring Equipment for Home Use: Pulse, Blood Pressure, Telemonitors, and Pacemaker Monitors

Number: 0548

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Congestive Heart Failure Telemonitoring:

Aetna considers home congestive heart failure telemonitoring devices experimental and investigational because such devices have not been shown to improve clinical outcomes compared to standard methods of heart failure monitoring (e.g., use of a standard scale, recording of weights in a diary that is shared with the physician, etc.).

Invasive Congestive Heart Failure Monitoring:

Aetna considers implantable congestive heart failure monitors (e.g., the Chronicle IHM System) experimental and investigational because such devices have not been shown to improve clinical outcomes compared to standard methods of heart failure monitoring.

Aetna considers an implantable wireless pulmonary artery pressure monitor (CardioMems) experimental and investigational for heart failure and all other indications.

Self-Contained Pacemaker Monitors:

Aetna 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.

A pacemaker controls cardiac arrhythmias by repeated electrical stimulation of the heart. Pacemaker monitoring equipment is needed to detect impending battery failure and to monitor the performance of the pacemaker. The design of the self-contained pacemaker monitor makes it possible for the member...
to monitor his or her pacemaker periodically and minimizes the need for regular visits to the outpatient department of the provider.

**Pulse Tachometers:**

*Note:* Pulse tachometers (pulse rate monitors, heart rate monitors) do not meet Aetna’s definition of covered durable medical equipment (DME) 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:**

*Notes:* Aetna considers home blood pressure monitors a medically necessary alternative to ambulatory blood pressure monitoring to confirm the diagnosis of hypertension in persons age 18 years of age and older who have elevated blood pressure readings in the office (greater than 140 systolic or 90 diastolic) and the following criteria are met:

I. the blood pressure cuff is prescribed by a physician;
II. arm devices only; and
III. correct cuff size assessed and provided by the vendor; and
IV. only one blood pressure cuff considered medically necessary per 5 years.

In addition, Aetna covers blood pressure monitors for members receiving hemodialysis or peritoneal dialysis in the home. In addition, blood pressure cuffs are covered for members with hypertension in pregnancy and have a DME rider.

Aetna considers automated oscillometer blood pressure 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 blood pressure monitors (see background).

**Non-Invasive Measurement of Central Blood Pressure**

Aetna considers non-invasive assessment of central blood pressure (e.g., SphygmoCor System) experimental and investigational because its effectiveness has not been established. See also CPB 0381 - Cardiovascular Disease Risk Tests.

**AngelMed Guardian Intracardiac Ischemia Monitoring Device**

Aetna considers the AngelMed Guardian intracardiac ischemia monitoring device experimental and investigational because of insufficient evidence in the peer-reviewed literature.

See also

- CPB 0019 - Holter Monitors and
- CPB 0025 - Automated Ambulatory Blood Pressure Monitoring.

**Background**

**Congestive Heart Failure Telemonitoring:**

Non-invasive telemonitoring for congestive heart failure involves the trans-telephonic transmission of weight, blood pressure (BP), heart rate (HR) 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 fewer days dead or hospitalized (the primary study endpoint) than patients assigned to NTS or UC. In this study, 426 patients recruited from hospitals in the Netherlands, the United Kingdom, and Germany with a recent (within the past 6 weeks) hospital admission for heart failure and left ventricular ejection fraction (LVEF) less than 40 % were assigned randomly to HTM, NTS, or UC in a 2:2:1 ratio. Patients were taking at least 40 mg per day of furosemide or equivalent, and at least 1 marker of increased risk. Home telemonitoring consisted of twice-daily patient self-measurement of weight, BP, HR, and rhythm with automated devices linked to a cardiology center. The NTS consisted of specialist nurses who were available to patients by telephone. Primary care physicians delivered UC. The primary end point was days dead or hospitalized with NTS versus HTM at 240 days. The investigators reported that, during 240 days of follow-up, there was no statistically significant difference in the days that were lost as the result of death or hospitalization for UC, NTS, and HTM. The number of admissions and mortality were similar among patients randomly assigned to NTS or HTM, but the mean duration of admission was less in patients assigned to HTM. The investigators concluded that “[f]urther investigation and refinement of the application of HTM are warranted because it may be a valuable role for the management of selected patients with heart failure.”

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.”

In a systematic review, Chaudhry et al (2007) examined the evidence on telemonitoring in patients with chronic heart failure. Interventions included telephone-based symptom monitoring (n = 5), automated monitoring of signs and symptoms (n = 1), and automated physiologic monitoring (n = 1). Two studies directly compared effectiveness of 2 or more forms of telemonitoring. Study quality and intervention type varied considerably. Six studies suggested reduction in all-cause and heart failure hospitalizations (14 % to 55 % and 29 % to 43 %, respectively) or mortality (40 % to 56 %) with telemonitoring. Of the 3 negative studies, 2 enrolled low-risk patients and patients with access to high quality care, whereas 1 enrolled a very high-risk Hispanic population. Studies comparing forms of telemonitoring demonstrated similar effectiveness. However, intervention costs were higher with more complex programs (8,383 dollars per patient per year) versus less complex programs (1,695 dollars per patient per year). The authors concluded that the evidence base for telemonitoring in heart failure is currently quite limited. Furthermore, an editorial published in the British Medical Journal (Grancelli and Ferrante, 2007), which addressed another systematic evidence review found similar results with simple telephone interventions compared to complex congestive heart failure telemonitoring.

Dang et al (2009) evaluated the evidence base for the use of home telehealth remote monitoring in elderly with congestive heart failure (CHF). The search was restricted to randomized controlled trials using either automated monitoring of signs and symptoms or automated physiologic monitoring. For this review, telephone-based monitoring of signs and symptoms was not considered remote monitoring. Studies were also excluded if they did not present outcomes related to healthcare utilization. A total of 9 studies met selection criteria, with interventions that varied greatly. Four 3-arm studies directly compared the effectiveness of 2 different interventions to usual care. Six of the 9 studies suggested a 27 % to 40 % reduction in overall admissions. Two 2-arm studies demonstrated a 40 % to 46 % reduction in HF-related admissions while 2 other 3-arm studies showed similar trends; however, this was not statistically significant. Three of 9 studies suggested a significant reduction in mortality (30 % to 67 %) and 3 studies showed significant reduction in healthcare utilization costs. Two studies suggested a 53 % to 62 % reduction in bed days of care. Two studies showed significant reduction in the number of Emergency Department visits. Three 2-arm studies and 1 3-arm study demonstrated significant overall improvement in outcomes with use of telemonitoring. Available data suggest that telemonitoring is a promising strategy. The authors stated that more data are needed to determine the ideal patient population, technology, and parameters, frequency and duration of telemonitoring, and the exact combination of case management and close monitoring that would assure consistent and improved outcomes with cost reductions in CHF.
Mortara and co-workers (2009) assessed the feasibility of a new system of HTM. The HTM system was used to monitor clinical and physiological parameters, and its effectiveness (compared with usual care) in reducing cardiac events in heart failure (HF) patients was evaluated. Measurements were patient-managed. From 2002 to 2004, a total of 461 HF patients (age 60 +/- 11 years, New York Heart Association class 2.4 +/- 0.6, left ventricular ejection fraction 29 +/- 7 %) were enrolled at 11 centers and randomized (1:2) to either usual outpatient care or HTM administered as 3 randomized strategies:

I. monthly telephone contact;
II. strategy 1 plus weekly transmission of vital signs; and
III. strategy 2 plus monthly 24-hr recording of cardiorespiratory activity.

Patients completed 81 % of vital signs transmissions, as well as 92 % of cardio-respiratory recordings. Over a 12-month follow-up, there was no significant effect of HTM in reducing bed-days occupancy for HF or cardiac death plus HF hospitalization. Post-hoc analysis revealed a heterogeneous effect of HTM in the 3 countries (Italy, Poland, and the United Kingdom) with a trend towards a reduction of events in Italy. The authors concluded that Home or Hospital in Heart Failure Study indicated that self-managed HTM of clinical and physiological parameters is feasible in HF patients, with surprisingly high compliance. Whether HTM contributes to a reduction of cardiac events requires further investigation.

Schmidt and colleagues (2010) reviewed the current status of health services research on telemonitoring, focusing on patients with chronic CHF. The Medline database was selectively searched for articles appearing from June 2001 to May 2008, with an emphasis on randomized, controlled trials. The available scientific data on vital signs monitoring are limited, yet there is evidence for a positive effect on some clinical endpoints, particularly mortality. However, any possible improvement of patient-reported outcomes, such as the quality of life, still remains to be demonstrated. The authors concluded that these findings suggested that telemonitoring is effective, yet there is no evidence for superior outcomes with any particular model of care incorporating telemonitoring (i.e., monitoring of vital signs versus structured telephone monitoring). A valid criticism is that the individual components of HTM have not yet been separately tested in order to compare their individual effects.

Polisena and associates (2010) conducted a systematic review of the literature about HTM compared with usual care. An electronic literature search was conducted to identify studies of HTM use in CHF patients. A total of 21 original studies on HTM for patients with CHF were included (n = 3,082). A random effects model was used to compute treatment effectiveness to measure the average effect of the intervention across all studies where the quantitative pooling of results was appropriate. Home telemonitoring reduced mortality (risk ratio = 0.64; 95 % confidence interval [CI]: 0.48 to 0.85) compared with usual care. Several studies suggested that HTM also helped to lower the number of hospitalizations and the use of other health services. Patient quality of life and satisfaction with HTM were similar or better than with usual care. Moreover, the authors stated that more studies of higher methodological quality are needed to provide more precise information regarding the potential clinical effectiveness of home telehealth interventions.

Koehler et al (2011) examined if physician-led remote telemedical management (RTM) compared with usual care would result in reduced mortality in ambulatory patients with CHF. A total of 710 stable CHF patients in New York Heart Association (NYHA) functional class II or III with a LVEF of less than or equal to 35 % and a history of HF decompensation within the previous 2 years or with a LVEF of less than or equal to 25 % were enrolled in this study. Patients were randomly assigned (1:1) to RTM or usual care. Remote telemedical management used portable devices for ECG, BP, and body weight measurements connected to a personal digital assistant that sent automated encrypted transmission via cell phones to the telemedical centers. The primary end point was death from any cause. The first secondary end point was a composite of cardiovascular death and hospitalization for HF. Baseline characteristics were similar between the RTM (n = 354) and control (n = 356) groups. Of the patients
assigned to RTM, 287 (81 %) were at least 70 % compliant with daily data transfers and no break for greater than 30 days (except during hospitalizations). The median follow-up was 26 months (minimum 12), and was 99.9 % complete. Compared with usual care, RTM had no significant effect on all-cause mortality (hazard ratio, 0.97; 95 % CI: 0.67 to 1.41; p = 0.87) or on cardiovascular death or HF hospitalization (hazard ratio, 0.89; 95 % CI, 0.67 to 1.19; p = 0.44). The authors concluded that in ambulatory patients with CHF, RTM compared with usual care was not associated with a reduction in all-cause mortality.

A systematic evidence review (Molloy et al, 2012) examined interventions to enhance adherence to medications in patients with heart failure identified randomized controlled studies of intensified interventions. The review found that all of the six studies of intensified patient care that used direct patient contact intervention showed a significant positive effect on adherence. However, of the five studies of intensified patient that used telephone or telemonitoring programs, only one led to increased adherence.

An assessment by the California Technology Assessment Forum (Tice, 2011) found that home telemonitoring for patients with heart failure does not meet CTAF TA Criterion 3 through 5 for safety, effectiveness and improvement in health outcomes. CTAF's systematic review of the literature identified 17 trials that randomized 6352 patients to evaluate the efficacy of home telemonitoring. The settings, patient populations, interventions, control groups, outcomes and length of follow-up varied widely between the studies. Because of the heterogeneity in the trials and their outcomes, CTAF performed no formal metaanalysis. The CTAF assessment noted that two large, high quality trials that randomized 2363 patients were published near the time of the CTAF assessment (Tele-HF, TIM-HF) (citing Chaudhry, et al., 2010 and Koehler, et al., 2011). CTAF noted that neither study found any benefit to home monitoring compared with usual care. Mortality was 11% in both groups in one study and 15% in both groups in the other study. In both studies, hospitalization rates were slightly higher in the home telemonitoring groups (Tele-HF 49% versus 47%; TIM-HF 44% versus 39%). The CTAF assessment observed that there were not even trends in favor of home telemonitoring. At the time of the CTAF assessment, there are at least two additional large studies that have yet to be published (TEHAF, OptiLink-HF); the CTAF assessment noted that preliminary results from one of the studies were negative. The CTAF assessment noted that the strongly positive findings in some of the randomized trials suggest that there are subgroups of patients with HF who benefit from some form of telemonitoring. The CTAF assessment stated, however, that the published literature to date does not clearly identify which patients are most likely to benefit and what combination of home monitoring technologies are required to obtain optimal results.

Kitsiou et al (2013) evaluated the methodology, quality, and reporting characteristics of prior reviews that have investigated the effects of HTM interventions in the context of chronic diseases. Ovid MEDLINE, the Database of Abstracts of Reviews of Effects (DARE), and Health Technology Assessment Database (HTA) of the Cochrane Library were electronically searched to find relevant systematic reviews, published between January 1966 and December 2012. Potential reviews were screened and assessed for inclusion independently by 3 reviewers. Data pertaining to the methods used were extracted from each included review and examined for accuracy by 2 reviewers. A validated quality assessment instrument, R-AMSTAR, was used as a framework to guide the assessment process. A total of 24 reviews, 9 of which were meta-analyses, were identified from more than 200 citations. The bibliographic search revealed that the number of published reviews has increased substantially over the years in this area and although most reviews focus on studying the effects of HTM on patients with CHF, researcher interest has extended to other chronic diseases as well, such as diabetes, hypertension, chronic obstructive pulmonary disease, and asthma. Nevertheless, an important number of these reviews appear to lack optimal scientific rigor due to intrinsic methodological issues. Also, the overall quality of reviews did not appear to have improved over time. While several criteria were met satisfactorily by either all or nearly all reviews, such as the establishment of an a priori design with inclusion and exclusion criteria, use of electronic searches on multiple databases, and reporting of studies characteristics, there were other important areas that needed improvement. Duplicate data extraction, manual searches of highly relevant journals, inclusion
of gray and non-English literature, assessment of the methodological quality of included studies and quality of evidence were key methodological procedures that were performed infrequently. Furthermore, certain methodological limitations identified in the synthesis of study results have affected the results and conclusions of some reviews. The authors concluded that despite the availability of methodological guidelines that can be utilized to guide the proper conduct of systematic reviews and meta-analyses and eliminate potential risks of bias, this knowledge has not yet been fully integrated in the area of HTM. Moreover, they stated that further efforts should be made to improve the design, conduct, reporting, and publication of systematic reviews and meta-analyses in this area.

Pandor and colleagues (2013) examined the clinical effectiveness and cost-effectiveness of HTM or structured telephone support (STS) strategies compared with usual care for adult patients who have been recently discharged (within 28 days) from acute care after a recent exacerbation of HF. A total of 14 electronic databases (including MEDLINE, EMBASE, PsycINFO and The Cochrane Library) and research registers were searched to January 2012, supplemented by hand-searching relevant articles and contact with experts. The review included randomized controlled trials (RCTs) or observational cohort studies with a contemporaneous control group that included the following remote monitoring (RM) interventions:

- **I.** TM (including cardiovascular implanted monitoring devices) with medical support provided during office hours or 24/7;
- **II.** STS programs delivered by human-to-human contact (HH) or human-to-machine interface (HM).

A systematic review and network meta-analysis (where appropriate) of the clinical evidence was carried out using standard methods. A Markov model was developed to evaluate the cost-effectiveness of different RM packages compared with usual care for recently discharged HF patients. Tele-monitoring 24/7 or using cardiovascular monitoring devices was not considered in the economic model because of the lack of data and/or unsuitability for the United Kingdom (UK) setting. Given the heterogeneity in the components of usual care and RM interventions, the cost-effectiveness analysis was performed using a set of costing scenarios designed to reflect the different configurations of usual care and RM in the UK. The literature searches identified 3,060 citations; 6 RCTs met the inclusion criteria and were added to the 15 trials identified from the previous systematic reviews giving a total of 21 RCTs included in the systematic review. No trials of cardiovascular implanted monitoring devices or observational studies met the inclusion criteria. The methodological quality of the studies varied widely and reporting was generally poor. Compared with usual care, RM was beneficial in reducing all-cause mortality for STS HH [hazard ratio (HR) 0.77, 95% credible interval (CrI): 0.55 to 1.08], TM during office hours (HR 0.76, 95% CrI: 0.49 to 1.18) and TM 24/7 (HR 0.49, 95% CrI: 0.20 to 1.18); however, these results were statistically inconclusive. The results for TM 24/7 should be treated with caution because of the poor methodological quality of the only included study in this network. No favorable effect on mortality was observed with STS HM. Similar reductions were observed in all-cause hospitalizations for TM interventions, whereas STS interventions had no major effect. A sensitivity analysis, in which a study was excluded because it provided better-than-usual support to the control group, showed larger beneficial effects for most outcomes, particularly for TM during office hours. In the cost-effectiveness analyses, TM during office hours was the most cost-effective strategy with an estimated incremental cost-effectiveness ratio (ICER) of £11,873 per quality-adjusted life-year (QALY) compared with usual care, whereas STS HH had an ICER of £228,035 per QALY compared with TM during office hours. Structured telephone support HM was dominated by usual care. Similar results were observed in scenario analyses performed using higher costs of usual care, higher costs of STS HH and lower costs of TM during office hours. The authors concluded that despite wide variation in usual care and RM strategies, cost-effectiveness analyses suggested that TM during office hours was an optimal strategy (in most costing scenarios). However, clarity was lacking among descriptions of the components of RM packages and usual care and there was a lack of robust estimation of costs. The authors stated that further research is needed in these areas.
Kitsiou and colleagues (2015) evaluated existing evidence from multiple systematic reviews on the effectiveness of home telemonitoring interventions for patients with CHF to inform policy makers, practitioners, and researchers. A comprehensive literature search was performed on Medline, Embase, Cinahl, and the Cochrane Library to identify all relevant, peer-reviewed systematic reviews published between January 1996 and December 2013. Reviews were searched and screened using explicit keywords and inclusion criteria. Standardized forms were used to extract data and the methodological quality of included reviews was appraised using the AMSTAR (assessing methodological quality of systematic reviews) instrument. Summary of findings tables were constructed for all primary outcomes of interest, and quality of evidence was graded by outcome using the GRADE (Grades of Recommendation, Assessment, Development, and Evaluation) system. Post-hoc analysis and subgroup meta-analyses were conducted to gain further insights into the various types of home telemonitoring technologies included in the systematic reviews and the impact of these technologies on clinical outcomes. A total of 15 reviews published between 2003 and 2013 were selected for meta-level synthesis. Evidence from high-quality reviews with meta-analysis indicated that taken collectively, home telemonitoring interventions reduced the relative risk of all-cause mortality (0.60 to 0.85) and heart failure-related hospitalizations (0.64 to 0.86) compared with usual care. Absolute risk reductions ranged from 1.4 % to 6.5 % and 3.7 % to 8.2 %, respectively. Improvements in HF-related hospitalizations appeared to be more pronounced in patients with stable HF: HR 0.70 (95 % CI: 0.34 to 1.5)]. Risk reductions in mortality and all-cause hospitalizations appeared to be greater in patients who had been recently discharged (less than or equal to 28 days) from an acute care setting after a recent HF exacerbation: HR 0.62 (95 % CI: 0.42 to 0.89) and HR 0.67 (95 % CI: 0.42 to 0.97), respectively. However, quality of evidence for these outcomes ranged from moderate-to-low suggesting that further research is very likely to have an important impact on the confidence in the observed estimates of effect and may change these estimates. The post-hoc analysis identified 5 main types of non-invasive telemonitoring technologies included in the systematic reviews:

I. video-consultation, with or without transmission of vital signs,
II. mobile telemonitoring,
III. automated device-based telemonitoring,
IV. interactive voice response, and
V. Web-based telemonitoring.

Of these, only automated device-based telemonitoring and mobile telemonitoring were effective in reducing the risk of all-cause mortality and HF-related hospitalizations. More research data are needed for interactive voice response systems, video-consultation, and Web-based telemonitoring to provide robust conclusions about their effectiveness. The authors concluded that future research should focus on understanding the process by which home telemonitoring works in terms of improving outcomes, identify optimal strategies and the duration of follow-up for which it confers benefits, and further investigate whether there is differential effectiveness between chronic HF patient groups and types of home telemonitoring technologies.

Invasive Congestive Heart Failure Monitoring:

Implantable hemodynamic monitoring devices have features that allow remote monitoring of hemodynamic data in patients with HF. 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 HR. It contains integrated circuitry, a lithium silver vanadium oxide battery with an approximate life of 3 years, and a bi-directional telemetry transmission coil hermetically sealed in a titanium can. The Chronicle IHM has an investigational device exemption in the United States, which allows use of the device in clinical trials.

Bourge et al (2008) reported on the outcomes of the COMPASS-HF (Chronicle Offers Management to Patients with Advanced Signs and Symptoms of Heart Failure) study, a randomized, single-blinded,
multi-center controlled study of the Chronicle IHM in 274 persons with NYHA class III or IV CHF. All study subjects had an emergency room visit or at least 1 prior HF-related hospitalization within 6 months of entering the study. The 274 successfully implanted patients were randomized to receive either optimal medical care alone (n = 140) or optimal medical care guided by results from hemodynamic measurements provided by the Chronicle IHM (n = 134). For the first 6 months, all IHM patients transmitted monitoring data weekly. Physicians for the control group were blocked from receiving IHM data. After 6 months, all physicians received IHM information for patient care. The primary end point of the study was a statistically significant reduction in treatment events, as defined by hospitalizations for HF, or emergency or urgent care center visits requiring intravenous therapy.

Patients whose physicians had access to IHM data had 22 % lower HF-related events; however this difference in the primary study end point was not statistically significant (p = 0.33). However, in the NYHA class III subgroup, there was a statistically significant 41 % reduction in the event rate for those patients whose physicians were accessing IHM data. The class IV (severe) subgroup did worse than the control group. The event rate over the course of the 6 months was 0.70 for IHM-monitored patients whose physicians could see the data, compared to 0.89 for the control group. Patients whose physicians had access to IHM data also had 21 % fewer hospitalizations. The relative risk of HF hospitalizations was 0.79 in the group with access to IHM data compared to the blocked access group, a difference that was statistically significant. A retrospective analysis of the time to first HF hospitalization showed a 36 % reduction (p = 0.03) in the relative risk of a HF-related hospitalization in the IHM group. In addition, the group whose physicians had access to IHM data had a 46 % increase in the proportion of patients who improved over the 6 months and a 34 % reduction in the proportion who worsened, compared to 35 % and 51 % in the control group, respectively. Primary safety related study end points were met, including freedom from system-related complications and freedom from pressure-sensor failure. System-related complications occurred in 8 % of the 277 patients who underwent implantation, and all but 4 complications were successfully resolved. There were no pressure-sensor failures after 6 months.

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. FDA panel concluded the trial failed to meet its primary efficacy end point. The assessment noted that, in the COMPASS-HF study, the most common device-related complication was lead dislodgement. 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.

Abraham (2013) noted that HF represents a major public health concern, associated with high rates of morbidity and mortality. A particular focus of contemporary HF management is reduction of hospital admission and re-admission rates. While optimal medical therapy favorably impacts the natural history of the disease, devices such as cardiac resynchronization therapy devices and implantable cardioverter defibrillators have added incremental value in improving HF outcomes. These devices also enable remote patient monitoring via device-based diagnostics. Device-based measurement of physiological parameters, such as intra-thoracic impedance and HR variability, provide a means to assess risk of worsening HF and the possibility of future hospitalization. Beyond this capability, implantable hemodynamic monitors have the potential to direct day-to-day management of HF patients to significantly reduce hospitalization rates. The use of a pulmonary artery pressure measurement system has been shown to significantly reduce the risk of HF hospitalization in a large RCT, the CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients (CHAMPION) trial. Observations from a pilot study also supported the potential use of a left atrial pressure monitoring system and physician-directed patient self-management paradigm; these observations are under further investigation in the ongoing LAPTOP-HF trial.

The CardioMEMS HF System is an implantable device that is used to monitor heart rate and
pulmonary artery (PA) pressure in certain individuals with HF. A small, paper clip-sized sensor is implanted into the pulmonary artery during a heart catheterization procedure. Once the device is implanted and the individual returns home, the Patient Electronics System uses wireless technology to read the PA pressure measurements and then transmits the information to the physician. Individuals purportedly may obtain a daily reading with the system and their physician can make medication adjustments based on the information received. The recipient of the device must be able to tolerate two types of anticoagulation medication for one month after the implantation procedure.

On May 28, 2014, the FDA cleared the CardioMEMS Heart Failure System for use in monitoring the heart rates and pulmonary arterial pressures of individuals with NYHA Class III heart failure who have been placed in the hospital for heart failure within the previous 12 months (FDA, 2014).

The Champion heart failure sensor is a capsule-sized (15 mm by 3 mm) wireless microelectromechanical (MEMS) device that is permanently implanted into the pulmonary artery to monitor PAP and cardiac output (Optum, 2014). The pressure-sensitive sensor consists of a coil and capacitor sealed in silicone. Two nitinol loops anchor the hemodynamic sensor into place within the pulmonary artery branch. The battery-free sensor is powered by external radiofrequency energy from an external antenna wand. Pressure changes cause shifts in the sensor's resonant frequency, which is picked up by the antenna. The patient uses the wand to take daily 20-second readings from the Champion implant, and the antenna transmits the gathered data to a secure Web site for access by health care providers who can tailor the patient's medication according to the readings. The Champion device is delivered through the femoral vein using a preloaded Swan-Ganz catheter-based system that advances the device into the pulmonary artery. After the procedure, which takes place in a catheterization lab, patients remain in the hospital overnight for observation. Anticoagulant therapy is given for 1 month after device implantation, followed by daily aspirin therapy.

Abraham et al (2011) reported on the CHAMPION trial, a single-blind trial that found a reduced rate of hospital admission with the CardioMEMS implantable hemodynamic monitoring system. Patients with NYHA class III heart failure, irrespective of the left ventricular ejection fraction, and a previous hospital admission for heart failure were enrolled in 64 centers in the United States. They were randomly assigned by use of a centralized electronic system to management with a wireless implantable hemodynamic monitoring (W-IHM) system (treatment group) or to a control group for at least 6 months. Only patients were masked to their assignment group. In the treatment group, clinicians used daily measurement of pulmonary artery pressures in addition to standard of care versus standard of care alone in the control group. The primary efficacy end-point was the rate of heart-failure-related hospitalizations at 6 months. The safety end-points assessed at 6 months were freedom from device-related or system-related complications (DSRC) and freedom from pressure-sensor failures. All analyses were by intention to treat. In 6 months, 83 heart-failure-related hospitalizations were reported in the treatment group (n = 270) compared with 120 in the control group (n = 280; rate 0.31 versus 0.44, hazard ratio [HR] 0.70, 95 % CI: 0.60 to 0.84, p < 0.0001). During the entire follow-up (mean 15 months [SD 7]), the treatment group had a 39 % reduction in heart-failure-related hospitalization compared with the control group (153 versus 253, HR 0.64, 95 % CI: 0.55 to 0.75; p < 0.0001). Eight patients had DSRC and overall freedom from DSRC was 98.6 % (97.3 to 99.4) compared with a pre-specified performance criterion of 80 % (p < 0.0001); and overall freedom from pressure-sensor failures was 100 % (99.3 to 100.0).

Commenting on this study, an accompanying editorialist (Krum, 2011) observed that there was a clear risk of overly aggressive diuresis or vasodilation to bring down raised pulmonary artery pressures in the intervention group in which these pressures were known. However, few data were provided on adverse events specifically related to drug changes, such as dizziness or postural hypotension. Furthermore, no information was given about what drugs were changed in this trial, which the editorialist said was surprising because these treatment changes are the presumed reason for the achieved differences in clinical outcomes between the groups. The editorialist stated that we will have to await future reports to determine exactly how the reductions in hospital admission for heart failure were achieved in CHAMPION. The editorialist also noted that, although patients generally received
best-practice background therapy (as reflected by low event rates in the control group), it was not clear whether any (or how many) were also receiving adjustments to their therapy guided by measurement of B-type natriuretic peptide, which would provide useful and complementary information for ongoing management.

Abraham and colleagues (2014) stated that implantable monitoring devices have been developed to detect early evidence of HF decompensation, with the hypothesis that early detection might enable clinicians to commence therapy sooner than would otherwise be possible, and potentially to reduce the rate of hospitalization. In addition to the usual challenges inherent to device trials (such as the difficulty of double-blinding and potential for bias), studies of implantable monitoring devices present unique difficulties because they involve assessment of therapeutic end-points for diagnostic devices.

Problems include the lack of uniform approaches to treatment in study protocols for device alerts or out-of-range values, and the requirement of levels of evidence traditionally associated with therapeutic devices to establish safety and effectiveness. In this review, the approaches used to deal with these issues are discussed, including the use of objective primary end-points with blinded adjudication, identical duration of follow-up and number of encounters for patients in active monitoring and control groups, and treatment recommendations between groups that are consistent with international guidelines. The authors concluded that remote monitoring devices hold promise for reducing the rate of hospitalization among patients with HF. However, optimization of regulatory approaches and clinical trial design is needed to facilitate further evaluation of the effectiveness of combining health information technology and medical devices.

Benza and associates (2015) conducted a retrospective analysis of the CHAMPION trial of an implantable hemodynamic monitor (IHM) in 550 NYHA Functional Class III HF patients, regardless of LVEF or HF etiology. These investigators evaluated clinical variables, changes in medical therapy, HF hospitalization rates and survival in patients with and without WHO Group II pulmonary hypertension (PH). Data were obtained for 314 patients (59 %) who had WHO Group II PH. Patients without PH were at significantly lower risk for mortality than PH patients (hazard ratio [HR] 0.31, 95 % CI: 0.19 to 0.52, p < 0.0001). Pulmonary hypertension patients had higher HF hospitalization rates than non-PH patients (0.77/year versus 0.37/year; HR 0.49, 95 % CI: 0.39 to 0.61, p < 0.001). In patients with and without PH, ongoing knowledge of hemodynamic data resulted in a reduction in HF hospitalization for PH patients (HR 0.64, 95 % CI: 0.51 to 0.81, p = 0.002) and for non-PH patients (HR 0.60, 95 % CI: 0.41 to 0.89, p = 0.01). Among PH patients, there was a reduction in the composite end-point of death and HF hospitalization with ongoing knowledge of hemodynamics (HR 0.74, 95 % CI: 0.55 to 0.99, p = 0.04), but no difference in survival (HR 0.78, 95 % CI: 0.50 to 1.22, p = 0.28). The authors concluded that WHO Group II PH is prevalent and identified HF patients at risk for adverse outcomes. Ongoing knowledge of hemodynamic variables may allow for more effective treatment strategies to reduce the morbidity of this disease.

The California Technology Assessment Forum (CTAF) (Ollendorf et al, 2015) completed a clinical comparative effectiveness review of the CardioMEMS HF System for CHF. The review concluded that the current body of evidence was promising but inconclusive: "For patients with Class III CHF with either reduced or preserved ejection fraction who have been hospitalized in the prior 12 months, we judge there to be moderate certainty of a small net benefit for the CardioMEMS HF System compared with usual monitoring of patients’ signs and symptoms. There is moderate certainty because while the CHAMPION trial indicated that patients had fewer hospitalizations when care was informed by the CardioMEMS HF System, the results of the CHAMPION study are limited by concerns regarding the potential confounding influence of the study nurse on the superior outcomes in the treatment arm. In addition, while post-hoc analyses have been presented illustrating reductions in cardiovascular mortality with CardioMEMS, there have been no published data from trials powered to detect mortality differences. It seems reasonable to surmise that ongoing post-marketing trials evaluating the device may demonstrate a wide variety of outcomes, from substantial net health benefit to a small likelihood of overall 'negative' benefit given the potential harms associated with device placement. Therefore, we judge the current body of evidence on CardioMEMS to be ‘promising but inconclusive’ using the ICER Evidence Rating framework".
Sandhu and associates (2016) evaluated the cost-effectiveness of the CardioMEMS device in patients with CHF. These researchers developed a Markov model to determine the hospitalization, survival, quality of life, cost, and incremental cost-effectiveness ratio of CardioMEMS implantation compared with usual care among a CHAMPION trial cohort of patients with HF. They obtained event rates and utilities from published trial data; and used costs from literature estimates and Medicare reimbursement data. These investigators performed subgroup analyses of preserved and reduced EF and an exploratory analysis in a lower-risk cohort on the basis of the CHARM (Candesartan in Heart failure: Reduction in Mortality and Morbidity) trials. CardioMEMS reduced lifetime hospitalizations (2.18 versus 3.12), increased QALYs (2.74 versus 2.46), and increased costs ($176,648 versus $156,569), thus yielding a cost of $71,462 per QALY gained and $48,054 per life-year gained. The cost per QALY gained was $82,301 in patients with reduced EF and $47,768 in those with preserved EF. In the lower-risk CHARM cohort, the device would need to reduce hospitalizations for HF by 41% to cost less than $100,000 per QALY gained. The cost-effectiveness was most sensitive to the device’s durability. The authors concluded that in populations similar to that of the CHAMPION trial, the CardioMEMS device is cost-effective if the trial effectiveness is sustained over long periods; they stated that post-marketing surveillance data on durability will further clarify its value.

Vanoli and colleagues (2016) noted that HF is a pandemic condition that is challenging cardiology today. Remote monitoring of physiological data, obtained through self-reporting via telephone calls or, automatically, using external devices is a potential novel approach to implement management of patients with HF and reduce hospitalization rates. Relatively large but, sometimes, contradicting information exists about the effectiveness of remote monitoring via different non-invasive approaches to reduce the economic and social burden of HF management. This leaves still partly unaddressed this critical issue and generates the need for new approaches. The CardioMEMS device that can chronically monitor pulmonary pressures from a small microchip inserted transvenously in the pulmonary artery appears to represent an innovative tool to challenge hospitalization rates. Consecutive analyses from the CHAMPION study had indeed documented the effectiveness of the CardioMEMS in the remote monitoring of the pulmonary circulation status of patients with HF and in providing adequate information to optimally manage such patients with the final result of a significant hospitalization rate reduction. The authors concluded that overall the reports from the CHAMPION study encouraged the use of CardioMEMS; but larger populations are needed to definitively prove its value.

Wang and Frishman (2017) noted that HF affects over 5.8 million patients in the United States, and can be very costly due to the number of hospitalizations and re-hospitalizations during the final years of life. Due to the large number of hospitalizations for HF exacerbations, effective methods for preventing these occurrences are necessary. Improvements in the outpatient treatment of HF, aided by non-invasive and invasive home monitoring methods, can reduce the number of hospitalizations.

Pulmonary pressure monitoring through the CardioMEMS system provides one method of hemodynamic assessment of patients. The effectiveness of the CardioMEMS system in reducing the number of HF exacerbations has been explored in the CHAMPION trial (CardioMEMS Heart Sensor Allows Monitoring of Pressures to Improve Outcomes in NYHA Functional Class III Heart Failure Patients), which demonstrated a reduction in hospitalizations for HF exacerbations in patients whose medical management was guided by adjusting medications based on pulmonary pressures compared with clinical signs and symptoms. Retrospective analyses suggested that HF patients of certain subgroups, including those with left heart dysfunction and those with preserved LVEF, could benefit from pulmonary pressure monitoring in controlling their HF. The authors concluded that larger studies are needed to examine if mortality can be reduced with pulmonary pressure monitoring.

An UpToDate review on “Strategies to reduce hospitalizations in patients with heart failure” (Horwitz and Krumholz, 2017) states that “Implantable hemodynamic monitoring is of uncertain efficacy and thus not recommended. The wireless CardioMEMS pulmonary artery monitoring device has been approved by the United States Food and Drug Administration to monitor pulmonary artery pressure and heart rate in patients with NYHA class III HF who have been hospitalized during the previous year.
Further study is needed to determine the efficacy and safety of this device ... the efficacy of the CardioMEMS device is uncertain given concerns raised about potential bias introduced in the conduct of the CHAMPION trial (including interaction between the trial sponsor and clinical investigators on certain treatment group subjects) and the analysis of data”.

Furthermore, an UpToDate review on “Treatment and prognosis of heart failure with preserved ejection fraction” (Borlaug and Colucci, 2017) states that “The wireless CardioMEMS pulmonary artery monitoring device is approved by the United States Food and Drug Administration to monitor pulmonary artery pressure and heart rate in patients with NYHA class III HF who have been hospitalized during the previous year. Further study is needed to determine the efficacy and safety of this device. The CHAMPION randomized, single-blind trial found that transmission of pulmonary artery pressure data from the device reduced HF-related hospitalizations at six months (31 versus 44 %, HR 0.70, 95 % CI 0.60 to 0.84). There was a 1.5 % rate of device- or system-related complications. An exploratory subgroup analysis found that device-guided management reduced HF-related hospitalization in patients with preserved LVEF (≥ 40 % or ≥ 50 %), as well as in patients with LVEF < 40 %. However, the efficacy of the CardioMEMS device in this population has not been established”.

**Home Blood Pressure Monitor for Hypertension Screening in Adults**

The U.S. Preventive Services Task Force (2015) recommends screening for high blood pressure in adults aged 18 years or older. The USPSTF recommends obtaining measurements outside of the clinical setting for diagnostic confirmation before starting treatment. The Task Force states that ambulatory blood pressure monitoring and home blood pressure monitoring may be used to confirm a diagnosis of hypertension after initial screening. The USPSTF found convincing evidence that ambulatory blood pressure monitoring is the best method for diagnosing hypertension. Although the criteria for establishing hypertension varied across studies, there was significant discordance between the office diagnosis of hypertension and 12- and 24-hour average blood pressures using ambulatory blood pressure monitoring, with significantly fewer patients requiring treatment based on ambulatory blood pressure monitoring. Elevated ambulatory systolic blood pressure was consistently and significantly associated with increased risk for fatal and nonfatal stroke and cardiovascular events, independent of office blood pressure. For these reasons, the USPSTF recommends ambulatory blood pressure monitoring as the reference standard for confirming the diagnosis of hypertension. The USPSTF states that home blood pressure monitoring using appropriate protocols is an alternative method of confirmation if ambulatory blood pressure monitoring is not available.

**Automated Oscillometer Blood Pressure Monitors:**

Barker et al (2000) stated that according to the criteria of the British Hypertension Society, neither the Dinamap 8100 nor the Omron M1 can be recommended for use in children in clinical situations in which accuracy of the absolute measurement is required.

Beaubien and colleagues (2002) reported that the Dinamap yields inaccurate estimates of both systolic and diastolic BP even under standardized, and thus optimal, conditions. This inaccuracy is exaggerated at higher BP (over 160/90 mm Hg), although the number of measurements at higher pressures was small. The authors recommended that this device not be used when accurate BP measurement is needed for therapeutic decision-making.

Chang and colleagues (2003) evaluated the variability in observed BP associated with use of the Dinamap monitor (Dinamap PRO 100) and estimated the contributions of various factors to that variability. In 60 volunteers (30 aged 23 to 35 years and 30 aged 54 to 82 years), the authors obtained 30 simultaneous paired BP measurements in both arms at 1-min intervals. Variability, defined as the between-arm difference in BP measurements, was analyzed using a mixed-effects linear regression model. A total of 1,800 paired BP measurements were obtained. These researchers found that only 50 % of paired simultaneous BP measurements obtained were in agreement within 4 mm Hg for
systolic BP or within 3 mm Hg for diastolic BP. Residual variability, attributable to the intrinsic inaccuracy of the device, accounted for 64 to 82 % of the total systolic and diastolic BP variability. The majority of variability in BP measurement was due to the device as used under the study conditions.

Textor et al (2003) reported that 26 % (62 of 238) potential donors with excellent kidney function were mis-classified as hypertensive with clinic oscillometric measurements (Dinamap) alone. Ramanathan et al (2003) claimed that there is no role for standard automated oscillometric devices (Dinamap) in the calculation of ankle-brachial pressure index in the vascular clinic.

Afsal et al (2004) examined if there are differences in BP measurements taken using either automated oscillometric machines (Dinamap BP8800 and Omron Hem 713) or a random zero Hawksley sphygmomanometer in stable healthy renal transplant outpatients. These investigators concluded that there were no significant observer bias or cardiovascular artifacts. Intra-machine variability was small. Blood pressure measurements using Dinamap and Omron could lead to a difference of up to 30 mm Hg higher or 15 mm Hg lower than Hawksley random zero BP readings. Though widely used for convenience, automated oscillometric measures of BP in the renal transplant clinic are not optimal.

Dannevig et al (2005) concluded that BP should preferably be measured invasively in severely ill neonates and preterm infants, being aware of pitfalls with measurements using different oscillometer monitors and the size/arm circumference of the infant.

The BpTRU™ is an automated device that takes serial BP measurements in a physician’s office. The Canadian Agency for Drugs and Technologies in Health (Allison, 2006) stated that preliminary data from non-randomized, uncontrolled studies suggested that the average of 5 BP measurements by means of the BpTRU, taken while the patient is alone, more reliably reflects resting BP compared to standard manual measurements taken with a stethoscope and sphygmomanometer. Moreover, the report noted that more controlled studies are needed to compare BpTRU measurements at specific interval settings to standard measurements taken by trained clinicians across a spectrum of patients. This evidence is needed before specific recommendations can be made in guidelines regarding which BP monitor should be used preferentially in a physician’s office.

Fischell et al (2010) conducted the first clinical studies of intracardiac ST-segment monitoring in ambulatory humans. The authors reported that intracardiac monitoring was performed in 37 patients at high risk for acute coronary syndromes and the implanted monitor continuously evaluated ST segments as sensed by a conventional pacemaker right ventricle apical lead. Patients were alerted to detected ischemic events. The patients were followed for a median of 1.52 years. Four patients had ST segment changes of greater than or equal to 3 standard deviations of their normal daily range, in the absence of an elevated heart rate. In combination with immediate hospital monitoring, the results led to angiogram and/or intravascular ultrasonographic confirmation of thrombotic coronary occlusion/ruptured plaque. The authors concluded that shifts exceeding 3 standard deviations from a patient's daily intracardiac ST-segment range may be a sensitive/specific marker for thrombotic coronary occlusion and that patient alerting was associated with a median alert-to-door time of 19.5 minutes for patients at high risk of recurrent coronary syndromes, who typically present with 2 to 3 hour delays.

AngelMed Guardian

The AngelMed Guardian System is an implantable cardiac device that has not received U.S. Food and Drug Administration (FDA) approval. It is suggested to measure ST elevation changes and possible impending heart attack via real-time ECG. The system includes an internal implantable device, approximately the size of a pacemaker, with a lead placed into the heart, a pager and a programming device that monitors the electrical activity of the heart. A physician programs the device to recognize specific changes in the heart signals. The pager is worn by the individual at all times. When the system detects changes in the heart’s predetermined electrical signals, the pager vibrates, beeps and flashes, alerting the individual to seek immediate medical attention. Information from the device can be
The AngelMed Guardian implantable device records cardiac data and detects ischemic events through use of a standard pacemaker intracardiac lead placed in the right ventricular apex. The AngelMed Guardian detects acute ischemic events by analyzing ST-segment shifts, and if a shift is detected as greater than a heart rate-dependent programmable threshold, the device will generate an emergency alert signal. As of 2009, the AngelMed Guardian had been implanted in 55 people in the United States and Brazil (Hopenfeld et al, 2009).

The AngelMed Guardian remains an investigational device in the United States (AngelMed, 2012). Currently, a prospective, randomized multicenter study of subjects with a high-risk of having a myocardial infarction (MI) due to acute coronary syndrome or bypass surgery is underway. Subjects are being recruited in to the AngelMed for Early Recognition and Treatment of STEMI (ALERTS) Study, which has an open-label, crossover design; the primary efficacy objective is to determine whether the Guardian System reduces the composite of cardiac or unexplained death, new Q-wave MI and time-to-door for a confirmed occlusive event at a medical facility (Angel Medical Systems, 2012).

Non-Invasive Measurement of Central Blood Pressure

Laugesen et al (2013) noted that the SphygmoCor is used for non-invasive assessment of ascending aortic BP. However, the validity of the SphygmoCor transfer function had not been tested in an exclusively type 2 diabetic patient sample. Calibration with systolic (SBP) and diastolic (DBP) brachial BP has previously been associated with substantial imprecision of central BP estimates. These investigators hypothesized that different non-invasive calibration strategies might improve the accuracy of the estimated ascending aortic BPs. In 34 patients with type 2 diabetes, these researchers estimated ascending aortic SBP and DBP using the SphygmoCor device and compared these data with invasively recorded data. The validity of the transfer function was assessed by calibrating with invasively recorded DBP and mean BP (MBP). The influence of non-invasive calibration strategies was assessed by calibrating with brachial oscillometric SBP+DBP versus DBP+MBP using a form factor (ff) of 0.33 and 0.40, respectively. When calibrating with invasive BP, the difference between estimated and invasively measured ascending aortic SBP and DBP was -2.3 ± 5.6/1.0 ± 0.9 mm Hg.

When calibrating with oscillometric brachial BPs, the differences were -9.6 ± 8.1/14.1 ± 6.2 mm Hg (calibration with SBP and DBP), -8.3 ± 11.7/13.9 ± 6.1 mm Hg (DBP and MBP; ff = 0.33), and 1.9 ± 12.2/14.1 ± 6.2 mm Hg (DBP and MBP; ff = 0.40), respectively. Calibration with the average of 3 brachial BPs did not improve accuracy. The authors concluded that the SphygmoCor transfer function seems valid in patients with type 2 diabetes. They stated that non-invasive calibration with DBP and MBP (ff = 0.40) enables accurate estimation of mean ascending aortic SBP at the group level; however, the wide limits of agreement indicate limited accuracy in the individual patient.

Omboni et al (2015) compared central BP and vascular indices estimated non-invasively over the 24 hours between normotensive volunteers and hypertensive patients by a pulse wave analysis of ambulatory BP recordings. Digitalized waveforms obtained during each brachial oscillometric BP measurement were stored in the device memory and analyzed by the validated Vasotens technology. Averages for the 24 hours and for the awake and asleep sub-periods were computed. A total of 142 normotensives and 661 hypertensives were evaluated. Overall, 24-hour central BP, pulse wave velocity (PWV), and aortic augmentation index (AI) were significantly higher in the hypertensive group than in the normotensive group (119.3 versus 105.6 mm Hg for SBP, 75.6 versus 72.3 mm Hg for DBP, 10.3 versus 10.0 m/sec for aortic PWV, -9.7 versus -40.7 % for peripheral AI, and 24.7 versus 11.0 % for aortic AI), whereas reflected wave transit time (RWTT) was significantly lower in hypertensive patients (126.6 versus 139.0 ms). After adjusting for confounding factors a statistically significant between-group difference was still observed for central BP, RWTT, and peripheral AI. All estimates displayed a typical circadian rhythm. The authors concluded that non-invasive assessment of 24-hour arterial stiffness and central hemodynamics in daily life dynamic conditions may help in assessing the arterial function impairment in hypertensive patients.
Xiao et al (2015) examined the differences in central hemodynamic indices between hypertensive and normotensive subjects and identified the BP index that the most strongly correlated with arterial stiffness and vascular damage markers. A cohort of 820 hypertensive patients and 820 normotensive individuals matched for age and gender were enrolled in this study. These researchers measured carotid-femoral and carotid-radial PWV, aortic AI and central BP using pulse wave analysis and applanation tonometry. Plasma homocysteine (HCY), high-sensitivity C-reactive protein (hsCRP) and N-terminal pro-B-type natriuretic peptide (NT-proBNP) were also tested in these subjects. In both hypertensive and normotensive subjects, the central SBP and pulse pressure (PP) were significantly lower than brachial SBP and PP; this PP amplification was significantly lower in the normotensives (9.85 +/-6.55 mm Hg) than in the hypertensives (12.64 +/-6.69 mm Hg), but the amplification ratios were comparable between the 2 groups. Blood pressure and age were closely related with aortic arterial stiffness. Compared with normotensive subjects, hypertensive subjects had higher carotid-femoral PWV and AI, and showed significantly lowered PP amplification ratio with age. Central PP was more strongly related to arterial stiffness and vascular damage markers than the other pressure indices. Multi-variate analyses revealed that carotid-femoral PWV and aortic AI were strongly influenced by central PP but not by the mean BP or brachial PP. The authors concluded that central PP is a more direct indicator of central arterial stiffness and a better marker of vascular aging than other BP variables. They stated that these findings support the use of central BP as a treatment target in future trials.

The Conduit Artery Function Evaluation (CAFE) study, a substudy of the Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT), examined the impact of 2 different BP lowering-regimens (atenolol+/− thiazide-based versus amlopidine+/− perindopril-based therapy) on derived central aortic pressures and hemodynamics (Williams, et al., 2006). The CAFE study recruited 2199 patients in 5 ASCOT centers. Radial artery applanation tonometry and pulse wave analysis (Sphygmocor) were used to derive central aortic pressures and hemodynamic indexes on repeated visits for up to 4 years. Most patients received combination therapy throughout the study. Despite similar brachial systolic BPs between treatment groups (Delta0.7 mm Hg; 95% CI, -0.4 to 1.7; P=0.2), there were substantial reductions in central aortic pressures with the amlopidine regimen (central aortic systolic BP, Delta 4.3 mm Hg; 95% CI, 3.3 to 5.4; P<0.0001; central aortic pulse pressure, Delta 3.0 mm Hg; 95% CI, 2.1 to 3.9; P<0.0001). Cox proportional-hazards modeling showed that central pulse pressure was significantly associated with a post hoc-defined composite outcome of total cardiovascular events/procedures and development of renal impairment in the CAFE cohort (unadjusted, P<0.0001; adjusted for baseline variables, P<0.05). The investigators concluded that BP-lowering drugs can have substantially different effects on central aortic pressures and hemodynamics despite a similar impact on brachial BP. Moreover, central aortic pulse pressure may be a determinant of clinical outcomes, and differences in central aortic pressures may be a potential mechanism to explain the different clinical outcomes between the 2 BP treatment arms in ASCOT. An accompanying editorial (Oparil, et al., 2006) stated that, "in the context of clinical trials, radial tonometry adds to our knowledge of the pharmacodynamic effects of vasoactive drugs. . . . Whether radial tonometry should be performed routinely in individual patients as a diagnostic or therapeutic indicator, however, remains a matter of considerable debate. At present, the technique is probably not quite ready for ‘prime time’ in routine clinical practice."

Weber et al (2011) reported that increased arterial wave reflections are independent predictors of renal as well as cardiorenal events in patients with chronic kidney disease. These investigators prospectively quantified wave reflections as pressure augmentation (AP) and augmentation index (AIx) using radial applanation tonometry and a transfer function, in 111 patients (mean age of 53.6 years; 71 men, 31 diabetics) with chronic kidney disease not requiring dialysis. Primary end-point was a composite of doubling of serum creatinine, need for dialysis, and transplantation. Secondary end-point was a combination of renal and cardiovascular events. After a mean follow-up of 41.3 months, 37 and 46 patients reached the primary and the secondary end-point. AIx and AP proved statistically significant predictors of the renal endpoint (p < 0.05 for all), with a 2.5- and 3-fold increased risk for patients in the highest versus the lowest tertile, respectively. After adjustment for mean blood pressure (MBP), age, gender, diabetes, serum albumin, hemoglobin, urine
albumin/creatinine ratio, and renal function at baseline, Alx (hazard ratio [HR] 1.474/10 % increase in Alx, p = 0.04) as well as AP (HR 1.559/10 mm Hg increase in AP, p = 0.04) remained significant predictors of the renal end-point. In addition, Alx and AP were significant (p < 0.05) predictors of the combined cardiorenal end-point in univariate analysis and multivariable models. An commentary noted that pulse wave velocity was not measured in this study (Payne, 2011). The commentator concluded: "Where do we go from here?" The authors note that Alx may be a suitable target for intervention, and indeed propose that a trial be undertaken to determine whether therapeutically targeting wave reflections independent of blood pressure reduction would lessen CKD progression. This may also partly address the unanswered question of causality. Unfortunately, we still lack any suitable pharmacological interventions to achieve this, as current options for lowering Alx all have significant blood pressure lowering effects. Furthermore, given the inextricable relationship between Alx and blood pressure, targeting one of these factors and not the other is perhaps inappropriate, and indeed the current findings may support the use of antihypertensive agents which also reduce Alx. Regardless of the therapeutic intervention employed, measuring Alx may facilitate earlier and more aggressive targeting of at-risk patients, and larger studies are certainly justified to explore the prognostic value of Alx in more detail".

Sharman et al (2013) sought to determine the usefulness of central BP to guide hypertension management. The investigators conducted a prospective, open-label, blinded–end point study in 286 patients with hypertension randomized to treatment decisions guided by best-practice usual care (n = 142; using office, home, and 24-hour ambulatory BP) or, in addition, by central BP intervention (n = 144; using SphygmoCor). Therapy was reviewed every 3 months for 12 months, and recommendations were provided to each patient and his/her doctor on anti-hypertensive medication titration. Outcome measures were as follows: medication quantity (daily defined dose), quality of life, and left ventricular mass (3-dimensional echocardiography). There was 92 % compliance with recommendations on medication titration, and quality of life improved in both groups (post-hoc p < 0.05). For usual care, there was no change in daily defined dose (all p > 0.10), but with intervention there was a significant stepwise decrease in daily defined dose from baseline to 3 months (p = 0.008) and each subsequent visit (all p < 0.001). Intervention was associated with cessation of medication in 23 (16 %) patients versus 3 (2 %) in usual care (p < 0.001). Despite this, there were no differences between groups in left ventricular mass index, 24-hour ambulatory BP, home systolic BP, or aortic stiffness (all p > 0.05). The investigators concluded that guidance of hypertension management with central BP results in a significantly different therapeutic pathway than conventional cuff BP, with less use of medication to achieve BP control and no adverse effects on left ventricular mass, aortic stiffness, or quality of life. An accompanying editorial (Avolio et al, 2013) commented that "there is still insufficient evidence for central aortic BP to be integrated in guidelines for treatment and management of hypertension". The editorialist stated that trials are required to assess hard end-points, where subjects are followed up for a longer period (of the order of 5 years, similar to many other intervention studies). In addition, the design should be expanded where central aortic BP is measured in all subjects, but where one group is assessed by measurements of brachial cuff pressure but blind to the results of central BP and the other groups guided by the results of central BP but blind to the results of brachial BP.

Shaikh and colleagues (2016) stated that the relations of measures of arterial stiffness, pulsatile hemodynamic load, and endothelial dysfunction to atrial fibrillation remain poorly understood. To better understand the pathophysiology of atrial fibrillation, these investigators examined associations between non-invasive measures of vascular function and new-onset atrial fibrillation. The study sample included participants aged greater than or equal to 45 years from the Framingham Heart Study offspring and 3rd-generation cohorts. Using Cox proportional hazards regression models, these researchers examined relations between incident atrial fibrillation and tonometry measures of arterial stiffness (carotid-femoral pulse wave velocity), wave reflection (augmentation index), pressure pulsatility (central pulse pressure), endothelial function (flow-mediated dilation), resting brachial arterial diameter, and hyperemic flow. Atrial fibrillation developed in 407/5,797 participants in the tonometry sample and 270/3,921 participants in the endothelial function sample during follow-up (median of 7.1
years, maximum of 10 years). Higher augmentation index (hazard ratio, 1.16; 95 % CI: 1.02 to 1.32; \(p = 0.02\)), baseline brachial artery diameter (hazard ratio, 1.20; 95 % CI: 1.01 to 1.43; \(p = 0.04\)), and lower flow-mediated dilation (hazard ratio, 0.79; 95 % CI: 0.63 to 0.99; \(p = 0.04\)) were associated with increased risk of incident atrial fibrillation. Central pulse pressure, when adjusted for age, sex, and hypertension (hazard ratio, 1.14; 95 % CI: 1.02 to 1.28; \(p = 0.02\)) was associated with incident atrial fibrillation. Higher pulsatile load assessed by central pulse pressure and greater apparent wave reflection measured by augmentation index were associated with increased risk of incident atrial fibrillation. The authors concluded that vascular endothelial dysfunction may precede development of atrial fibrillation; and these measures may be additional risk factors or markers of subclinical cardiovascular disease associated with increased risk of incident atrial fibrillation.

Current leading medical professional association guidelines on hypertension, heart failure, diabetes, renal disease and assessment of cardiovascular disease risk have no recommendation for non-invasive measurement of blood pressure by pulse waveform analysis.

### CPT Codes / HCPCS Codes / ICD-10 Codes

*Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":*

#### Congestive Heart Failure Telemonitoring:

**CPT codes not covered for indications listed in the CPB:**

- **0302T** Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; complete system (includes device and electrode)
- **0303T** Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; electrode only
- **0304T** Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; device only
- **0305T** Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report
- **0306T** Interrogation device evaluation (in person) of intracardiac ischemia monitoring system with analysis, review, and report
- **0307T** Removal of intracardiac ischemia monitoring device

#### Invasive Congestive Heart Failure Monitoring:

**HCPCS codes not covered for indications listed in the CPB:**

- **C2624** Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components

#### Self-contained Pacemaker Monitors:

**CPT codes covered if selection criteria are met:**
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>93279</td>
<td>Programming device evaluation with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with physician analysis, review and report; single lead pacemaker system</td>
</tr>
<tr>
<td>93280</td>
<td>dual lead pacemaker system</td>
</tr>
<tr>
<td>93281</td>
<td>multiple lead pacemaker system</td>
</tr>
<tr>
<td>93282</td>
<td>single lead transvenous implantable defibrillator system</td>
</tr>
<tr>
<td>93283</td>
<td>dual lead transvenous implantable defibrillator system</td>
</tr>
<tr>
<td>93284</td>
<td>multiple lead transvenous implantable defibrillator system</td>
</tr>
<tr>
<td>93286</td>
<td>Peri-procedural device evaluation and programming of device system parameters before or after a surgery, procedure, or test with physician analysis, review and report; single, dual, or multiple lead pacemaker system</td>
</tr>
<tr>
<td>93287</td>
<td>single, dual, or multiple lead implantable defibrillator system</td>
</tr>
<tr>
<td>93288</td>
<td>Interrogation device evaluation (in person) with physician analysis, review and report, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead pacemaker system</td>
</tr>
<tr>
<td>93289</td>
<td>single, dual, or multiple lead transvenous implantable defibrillator system, including analysis of heart rhythm derived data elements</td>
</tr>
<tr>
<td>93290</td>
<td>implantable cardiovascular monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors</td>
</tr>
<tr>
<td>93292</td>
<td>wearable defibrillator system</td>
</tr>
<tr>
<td>93293</td>
<td>Transtelephonic rhythm strip pacemaker evaluation(s) single, dual, or multiple lead pacemaker system, includes recording with and without magnet application with physician analysis, review and report(s), up to 90 days</td>
</tr>
<tr>
<td>93294</td>
<td>Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system with interim physician analysis, review(s) and report(s)</td>
</tr>
<tr>
<td>93295</td>
<td>single, dual, or multiple lead implantable defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional</td>
</tr>
<tr>
<td>93296</td>
<td>single, dual, or multiple lead pacemaker system or implantable defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results</td>
</tr>
<tr>
<td>93297</td>
<td>Interrogation device evaluation(s) (remote), up to 30 days; implantable cardiovascular monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, physician analysis, review(s) and report(s)</td>
</tr>
</tbody>
</table>

**HCPCS codes covered if selection criteria are met:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0610</td>
<td>Pacemaker monitor, self-contained, (checks battery depletion, includes audible and visible check systems)</td>
</tr>
</tbody>
</table>
E0615 Pacemaker monitor, self-contained, checks battery depletion and other pacemaker components, includes digital/visible check systems

ICD-10 codes covered if selection criteria are met:
I46.2 - I49.9 Cardiac dysrhythmias
R00.1
Z95.0 Presence of cardiac pacemaker

Pulse Tachometers - no specific codes:

Blood Pressure Monitors and Stethoscopes:

Other CPT codes related to the CPB:
90935 - 90937 Hemodialysis

HCPCS codes covered if selection criteria are met:
A4660 Sphygmomanometer / blood pressure apparatus with cuff and stethoscope
A4663 Blood pressure cuff only
A4670 Automatic blood pressure monitor

ICD-10 codes covered if selection criteria are met:
I10 Essential primary hypertension [not covered for under age 18]
I12.0 Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease
I13.11 - I13.2 Hypertensive heart and chronic kidney disease [without heart failure and with stage 5 chronic kidney disease or end stage renal disease and with heart failure and with stage 5 chronic kidney disease, or end stage renal disease]
N17.0 - N19 Acute kidney failure and chronic kidney disease
O10.011 - O11.9 Proteinuria and hypertensive disorders in pregnancy, childbirth and the puerperium
O13.1 - O16.9 Elevated blood-pressure reading, without diagnosis of hypertension [not covered for under age 18]
Z99.2 Dependence on renal dialysis

Noninvasive assessment of central blood pressure (SphygmoCor System):

CPT codes not covered for indications listed in the CPB:
93050 Arterial pressure waveform analysis for assessment of central arterial pressures, includes obtaining waveform(s), digitization and application of nonlinear mathematical transformations to determine central arterial pressures and augmentation index, with interpretation and report, upper extremity artery, non-invasive

Intracardiac Ischemia Monitoring Devices (AngelMed Guardian):

CPT codes not covered for indications listed in the CPB:
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0302T</td>
<td>Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; complete system (includes device and electrode)</td>
</tr>
<tr>
<td>0303T</td>
<td>Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; electrode only</td>
</tr>
<tr>
<td>0304T</td>
<td>Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; device only</td>
</tr>
<tr>
<td>0305T</td>
<td>Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report</td>
</tr>
<tr>
<td>0306T</td>
<td>Interrogation device evaluation (in person) of intracardiac ischemia monitoring system with analysis, review, and report</td>
</tr>
<tr>
<td>0307T</td>
<td>Removal of intracardiac ischemia monitoring device</td>
</tr>
</tbody>
</table>

**The above policy is based on the following references:**


50. U.S. Food and Drug Administration (FDA). FDA approves first implantable wireless device with


ICER. CardioMEMS™ HF System (St. Jude Medical) and Sacubitril/Valsartan (Entresto™, Novartis) for Management of Congestive Heart Failure: Effectiveness, Value, and Value-Based Price Benchmarks. Draft Report. San Francisco, CA: California Technology Assessment Forum (CTAF); September 11, 2015.


77. McMurray JJ, Adamopoulos S, Anker SD, et al.; ESC Committee for Practice Guidelines. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012: The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association (HFA) of the ESC. Eur Heart J. 2012;33(14):1787-1847.


83. Piper MA, Evans CV, Burda BU, et al. Screening for High Blood Pressure in Adults: A


88. Borlaug BA, Colucci WS. Treatment and prognosis of heart failure with preserved ejection fraction. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed March 2017.
AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0548 Cardiovascular Monitoring Equipment for Home Use: Pulse, Blood Pressure, Telemonitors, and Pacemaker Monitors

There are no amendments for Medicaid.

www.aetnabetterhealth.com/pennsylvania updated 09/01/2017