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

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Policy 

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 (CardioMem) 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: Home blood pressure monitors (sphygmomanometers, blood pressure cuffs) and stethoscopes do not meet Aetna’s definition of covered DME in that they may be of use in the absence of illness and injury. Following Medicare rules, Aetna covers blood pressure monitors and stethoscopes only 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).

Noninvasive Measurement of Central Blood Pressure

Aetna considers noninvasive assessment of central blood pressure (e.g., SphygmoCor System) experimental and investigational because its effectiveness has not been established. See also CPB 381 - 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 physiologic 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
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five studies of intensified patient care 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 positive. 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 y stated that further research is needed in these areas.

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 intra-cardiac 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 readmission 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 CardiOmens 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.

On May 28, 2014, the FDA cleared the CardiOmens 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 New York Heart Association (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 endpoint was the rate of heart-failure-related hospitalizations at 6 months. The safety endpoints 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 vs 0.44, hazard ratio [HR] 0.70, 95% CI 0.60-0.84, 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 vs. 253, HR 0.64, 95% CI 0.55-0.75; p<0.0001). Eight patients had DSRC and overall freedom from DSRC was 98.6% (97.3-99.4) compared with a prespecified performance criterion of 80% (p<0.0001); and overall freedom from pressure-sensor failures was 100% (99.3-100.0).

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.

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.

Afzali 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.

The AngelMed Guardian is an implantable device which 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).

CPT Codes / HCPCS Codes / ICD-9 Codes

Congestive Heart Failure Telemonitoring:

CPT Codes not covered:

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

Self-contained Pacemaker Monitors:

CPT codes covered if selection criteria are met:

93279 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

93280 dual lead pacemaker system

93281 multiple lead pacemaker system

93282 single lead implantable cardioverter-defibrillator system

93283 dual lead implantable cardioverter-defibrillator system

93284 multiple lead implantable cardioverter-defibrillator system
93286 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

93287 single, dual, or multiple lead implantable cardioverter-defibrillator system

93288 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

93289 single, dual, or multiple lead implantable cardioverter-defibrillator system, including analysis of heart rhythm derived data elements

93290 implantable cardiovascular monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors

93292 wearable defibrillator system

93293 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

93294 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)

93295 single, dual, or multiple lead implantable cardioverter-defibrillator system with interim physician analysis, review(s) and report(s)

93296 single, dual, or multiple lead pacemaker system or implantable cardioverter-defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results

93297 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)

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

**E0610** Pacemaker monitor, self-contained, (checks battery depletion, includes audible and visible check systems)
Pacemaker monitor, self-contained, checks battery depletion and other pacemaker components, includes digital/visible check systems

**ICD-9 codes covered if selection criteria are met:**

- 427.0 - 427.9 Cardiac dysrhythmias V45.01
  - Cardiac pacemaker status

**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-9 codes covered if selection criteria are met:**

- 403.11 Benign hypertensive chronic kidney disease
- 403.91 Unspecified hypertensive chronic kidney disease
- 404.12 - 404.13 Benign hypertensive heart and chronic kidney disease, without heart failure and with chronic kidney disease or with heart failure and chronic kidney disease
- 404.92 - 404.93 Unspecified hypertensive heart and chronic kidney disease, without heart failure and with chronic kidney disease or with heart failure and chronic kidney disease
- 584.5 - 586 Renal failure
- 642.00 - 642.94 Hypertension complicating pregnancy, childbirth, and the puerperium
- V45.1 Renal dialysis status

**Noninvasive assessment of central blood pressure (SphygmoCor System):**

**CPT codes not covered for indications listed in the CPB:**
0311T  Non-invasive calculation and analysis of central arterial pressure waveforms with interpretation and report [SphygmoCor System]

**Intracardiac Ischemia Monitoring Devices (AngelMed Guardian):**

**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

The above policy is based on the following references:


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