Clinic Policy Title: Home monitoring: Blood pressure (BP) and weight

Clinical Policy Number: 17.01.05

Effective Date: January 1, 2017
Initial Review Date: October 19, 2016
Most Recent Review Date: October 19, 2016
Next Review Date: October, 2017

Related policies:

CP# 04.01.03 Ambulatory Blood Pressure Monitoring

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Keystone First when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First considers the use of home monitoring of blood pressure (BP) and body weight to be clinically proven and, therefore, medically necessary with the following conditions:

- Definitive diagnosis of heart failure and/or uncontrolled hypertension has been established.
- At least two documented, separate BP measurements taken in the hospital and/or in the physician's office are >140/90 mm Hg.
- At risk for re-admission for heart failure and/or hypertension.

Keystone First considers the use of home monitoring of blood pressure and weight to be clinically proven and, therefore, medically necessary when the following criteria are met:

- Member is under the care of primary care physician (PCP) or specialist (SP) to assess, evaluate and intervene one week post discharge and as prescribed by PCP.
- To improve and increase self-management:
- Member is educated and trained by professional:
To monitor and record weight in log as ordered by PCP or SP.
To monitor and record blood pressure in log.
- Use of validated instruments and systematic protocols as prescribed by their PCP.

Limitations:

All other uses of home monitoring for BP and body weight are not medically necessary.

Note: The following CPT/HCPCS code is not listed in the Pennsylvania Medicaid fee schedule:

A4670 - Automatic blood pressure monitor

Alternative covered services:

Home care services.

Background

Heart failure is a complex clinical syndrome resulting from any structural or functional cardiac disorder that impairs the ability of the ventricles to fill and/or eject blood. The cardinal manifestations of the syndrome are dyspnea and fatigue, fluid retention, or both. Continuity of care and seamless transitions from the inpatient to the outpatient setting are crucial aspects of optimal management. Assessment and tracking of the member’s heart failure symptoms (fluid status, via daily weights, and functional status) are keys to identifying clinical deterioration and avoiding inpatient episodes. Optimal management of underlying conditions (e.g., hypertension, coronary artery disease, diabetes) has been demonstrated to control symptoms and prevent disease progression.

Hypertension is a major independent risk factor for coronary artery disease, stroke, heart failure, and renal failure. One of every 3 American adults—or approximately 67 million adults (31%)—has hypertension (HTN). Home blood pressure monitoring is a convenient and inexpensive technique to monitor blood pressure in hypertensive patients. There are convincing data that home blood pressure monitoring is a good predictor of future cardiovascular risk, perhaps better than office blood pressure. Home blood pressure measurement can be standardized using validated instruments and systematic protocols; normative criteria have established home blood pressure >135/85 mm Hg as hypertensive. Home blood pressure monitoring has been shown to improve compliance and blood pressure control, and to reduce health care costs. Ongoing studies are evaluating management of hypertension based on home blood pressure readings compared with traditional office-based readings. Home blood pressure monitoring is particularly useful for evaluation of white coat hypertension and masked hypertension. (Mallick S. 2009).

The American Heart Association defines self-care as the decision-making process patients use to maintain physiological stability. Self-care includes multiple components, such as adhering to
medications, following diet and exercise recommendations, and actively monitoring for congestion. Self-
management extends this concept to the self-adjustment of the treatment regimen. Self-management is therefore a complex process: patients have to recognize a change in themselves (e.g., increasing edema), evaluate the symptom, decide to take action, implement a treatment strategy (e.g., taking an extra diuretic dose), and evaluate the response to therapy. Self-care and self-management behaviors are ultimately the responsibilities of the patient, even if they are frequently seen in the office or telephoned at home. (Riegel B et al. 2009)

According to Arya A et al (2009), despite optimal drug and device therapy, frequent hospitalizations due to decompensated heart failure remain an issue. Early detection of decompensation could prevent hospitalization in patients with congestive heart failure. The recently introduced Home Monitoring functionality of implanted devices is a promising new telecardiology technique which provides information on the status of heart failure. Home monitoring observation of heart failure patients could lead to early detection of preclinical decompensation, enable early intervention before clinical decompensation, and thus could prevent hospitalizations.

The IN-TIME study conducted by Ayers et al. was designed to assess the impact of home monitoring on the early detection of worsening congestive heart failure and the clinical status of heart failure patients.

Their design was approximately 620 patients prospectively randomized to patient management guided by home monitoring analysis or standard care and followed for 12 months. The endpoints committee adjudicated events in a blind fashion. The primary endpoint was a composite of all-cause mortality, unplanned hospitalization due to worsening heart failure, NYHA class and patient global self-assessment (Packer score). The study should complete recruitment during 2009 and report in late 2010.

**Searches**

Keystone First searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on September 2, 2016. Search terms were: “blood pressure, home monitoring, heart failure and body weight.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
• Guidelines based on systematic reviews.
• Economic analyses, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

N/A

Policy updates:

None.

Summary of clinical evidence:

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<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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| Bui AL et al. (2012) Home Monitoring for Heart Failure Management | **Key points:**
  • With a prevalence of 5.8 million in the United States alone, heart failure (HF) is a common syndrome associated with substantial morbidity, mortality, and healthcare expenditures.
  • Close to 1 million HF hospitalizations occur annually in the United States, with the majority of these resulting from worsening congestion in patients previously diagnosed with HF. An estimated $37.2 billion is spent each year on HF in the United States.
  • These statistics emphasize the need to develop and implement more effective strategies to assess, monitor, and treat HF. It has also become increasingly apparent that interventions geared toward identifying and monitoring subclinical congestion would be of value in the home management of chronic HF.
  • Earlier identification and treatment of congestion together with improved care coordination, management of comorbid conditions, and enhanced patient self-management may help to prevent hospitalizations in patients with chronic HF.
  • Such home monitoring extends from the promotion of self-care and home visitations to telemedicine and remote monitoring of external or implantable devices. This paper
| Moser et al. (2005) Rehospitalizations for heart failure (HF) | **Key points:**
  • Many rehospitalizations for heart failure (HF) are preventable as they are precipitated by modifiable factors. High early readmission rates suggest that patients commonly are discharged from HF hospitalizations with such problems unaddressed.
  • The purpose of this study was to describe the prevalence of multiple risk factors for rehospitalization in patients recently discharged from a hospital. Patients newly discharged from a hospital for HF exhibit many psychosocial and behavioral risk factors for rehospitalization, although they have been judged clinically stable. Spitalization for decompensated HF |
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<tr>
<td><strong>Scolaro KL et al (2005)</strong></td>
<td><strong>Key points:</strong></td>
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| Devices for ambulatory and home monitoring of blood pressure, lipids, coagulation, and weight management, part 1. | - Over 100 million people in the United States have one or more chronic diseases, such as diabetes, hypertension, and asthma. With the goal to improve health while reducing costs and the overall health care burden, ambulatory and home monitoring by pharmacists and patients are receiving more attention.  
- Ambulatory and home monitoring of blood pressure, cholesterol, coagulation, and weight management (including devices for assessing overweight and obese patients, heart rate monitors, and pedometers) are convenient for clinicians and patients. Such monitoring provides pharmacists with an opportunity to differentiate their practices.  
- Studies suggest that patients who are involved in ambulatory and home monitoring take a more active role in their health and may have better adherence to prescribed diet and medication regimens. Studies also show that ambulatory and home monitoring, if done correctly, provide clinicians with a large quantity of reliable readings for future therapeutic decisions.  
- Devices are also a means for pharmacists to increase their provision of pharmacy services. Ambulatory monitoring is billable in many clinic settings, and the many devices are available to assist patients and clinicians in monitoring blood pressure, lipids, coagulation, and weight management.  
- Familiarity with the devices will help in their proper selection and use of devices can be a profitable addition to prescription services. |
| **Scolaro KL et al (2005)** | **Key points:**                     |
| Devices for ambulatory and home monitoring of blood pressure, lipids, coagulation, and weight management, part 2. | - Studies suggest that patients who are involved in ambulatory and home monitoring take a more active role in their health and may have better adherence to a prescribed diet and medication regimens.  
- Studies also show that ambulatory and home monitoring, if done correctly, provide clinicians with a large quantity of reliable readings for future therapeutic decisions.  
- Devices are also a means for pharmacists to increase their provision of pharmacy services. Ambulatory monitoring is billable in many clinic settings, and the devices can be a profitable addition to prescription services. |
| **Oster ME et al (2015)** | **Key points:**                     |
| Association of Interstage Home Monitoring With Mortality, Readmissions, and Weight Gain: A Multicenter Study from the National Pediatric Cardiology Quality Improvement Collaborative | - To determine the association of various interstage home monitoring strategies with outcomes using a multicenter cohort with contemporary control subjects.  
- A retrospective cohort study using prospectively collected data from the National Pediatric Cardiology Quality Improvement Collaborative from 2008 to 2012.  
- Compared interstage mortality, unscheduled readmissions, and change in weight-for-age Z score for various home monitoring strategies of oxygen saturation (n=494) or weight (n=472), adjusting for sex, syndrome, tricuspid regurgitation, arch obstruction, and shunt type.  
- Overall interstage mortality was 8.1% and 47% had ≥1 unscheduled readmission.  
- Daily home weight monitoring was superior to no home weight monitoring (-0.15±0.18; P<0.01).  
- Home weight monitoring is associated with improved weight gain during the interstage period, but we did not find any benefits in other clinical outcomes for either home oxygen saturation monitoring or home weight monitoring. |
| **Hindricks G (2015)**    | **Key points:**                     |
| Heart failure and home    | - In-Time is the first implant-based remote monitoring RCT demonstrating significant benefits of implant-based home monitoring for patients with advanced heart failure. |
In the home monitoring arm of the trial: the number of heart failure patients with worsening of the clinical status was significantly reduced. Total mortality and cardiovascular mortality were significantly reduced compared to standard care.

Home monitoring based detection of changes in clinical status or technical events can trigger medical action that prevents worsening of heart failure.

**Glossary**

**Ambulatory blood pressure monitoring (ABPM)** — A noninvasive method of obtaining BP readings at regular intervals over 24 hours while the individual is in his/her own environment, representing a true reflection of the individual’s BP.

**Auscultatory method** — The process of measuring BP by listening to sounds (otherwise referred to as the Korotkoff technique).

**Dipping status** — Describes decreases in an individual’s BP during nighttime hours or when sleeping:
- **Dipper** — BP lowers by 10% – 20% during sleep.
- **Extreme dipper** — The difference between daytime BP and nighttime BP > 20%.
- **Nondipper** — Has a diminished nocturnal dip in BP.
- **Reverse dipper** — BP elevates to above daytime levels during the night.

**End-Organ Damage** — Damage occurring in major organs fed by the circulatory system (heart, kidneys, brain or eyes) which can sustain damage due to uncontrolled hypertension.

**Hypertension** — Persistently high systemic arterial blood pressure based on multiple readings:
- **Prehypertension** — SBP of 120 – 139 mm Hg and DBP of 80–89 mm Hg.
- **Stage 1 hypertension** — SBP of 140 – 159 mm Hg and DBP of 90–99 mm Hg.
- **Stage 2 hypertension** — SBP of ≥ 160 mm Hg or DBP of ≥ 100 mm Hg.

**Hypertrophy** — Abnormal enlargement of a part or organ; excessive growth.

**Hypotension** — Decreased or lowered blood pressure.

**Masked hypertension** — Normal BP in the office and elevated BP outside of the medical setting.

**Morbidity** — A diseased state or symptom; the incidence of disease or the rate of sickness in a specific community or group.

**Oscillometry method** — The process of measuring BP indirectly using an algorithm and determining the maximal pressure in the cuff during gradual deflation.

**Sustained hypertension** — Hypertension displayed by both clinics BP and ABPM.
References

Professional society guidelines/other:


http://circ.ahajournals.org/content/early/2016/05/18/CIR.0000000000000435. Accessed September 2, 2016

Peer-reviewed references:


Clinical trials:

Searched clinicaltrials.gov on September 1, 2016 using terms home monitoring and heart failure | Open Studies. 19 studies found, two relevant.


CMS National Coverage Determinations (NCDs):

No NCDs identified as of the writing of this policy.

Local Coverage Determinations (LCDs):

No LCDs identified as of the writing of this policy.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.
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<th>Description</th>
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<thead>
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<tr>
<td>I50.1-I50.9</td>
<td>Heart failure</td>
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<thead>
<tr>
<th>HCPCS Level II Codes</th>
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<tbody>
<tr>
<td>A4670</td>
<td>Automatic blood pressure monitor</td>
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