AmeriHealth Caritas considers the use of 24-hour ambulatory blood pressure monitoring to be clinically proven and, therefore, medically necessary to assist in the diagnosis of hypertension in adult members for the following indications (Whelton, 2018):

- Suspected white coat hypertension with a systolic blood pressure > 130 mm Hg but < 160 mm Hg or diastolic blood pressure > 80 mm Hg but < 100 mm Hg.
- Treated hypertension with office readings not at goal and home blood pressure monitoring suggests significant white coat effect.
- Treated hypertension with multiple drug therapies and office blood pressure within 10 mm Hg above goal.
- Known white coat hypertension:
  - Periodic monitoring to detect conversion to sustained hypertension.
- Suspected masked hypertension:
  - Office blood pressure consistently between 120-129 mm Hg/75-79 mm Hg in untreated members.
- Suspected masked uncontrolled (treated) hypertension and either:
  - Elevated home blood pressure readings prior to intensification of antihypertensive drug treatment.
  - Presence of target organ damage or increased overall cardiovascular disease risk and office readings at goal.
AmeriHealth Caritas considers the use of 24-hour ambulatory blood pressure monitoring to be clinically proven and, therefore, medically necessary to assist in the diagnosis of hypertension in pediatric members, using monitors that have been validated in a pediatric population and apply pediatric normative data, for any of the following clinical indications (Flynn, 2017):

- To confirm hypertension when office blood pressure measurements are at:
  - Elevated blood pressure category for 1 year or more, defined as: in children ages 1 to 13 years, in ≥ 90th percentile to < 95th percentile or 120/80 mm Hg to < 95th percentile (whichever is lower); in children ages 13 years or older, 120/< 80 mm Hg to 129/< 80 mm Hg.
  - Stage 1 hypertension defined as: in children ages 1 to 13 years, ≥ 95th percentile to < 95th percentile + 12 mmHg, or 130/80 mm Hg to 139/89 mm Hg (whichever is lower); in children ages 13 years or older, 130/80 mm Hg to 139/89 mm Hg.
  - Stage 2 hypertension after one week, defined as: in children ages 1 to 13 years, ≥ 95th percentile + 12 mm Hg, or ≥ 140/90 mm Hg (whichever is lower); in children ages 13 years or older, ≥ 140/90 mm Hg.

- To confirm treatment effectiveness.

- To diagnose suspected white coat hypertension.

- To routinely assess hypertension severity and determine the presence of abnormal circadian blood pressure patterns in the presence of high-risk conditions, including, but not limited to:
  - Secondary hypertension.
  - Chronic kidney disease or renal abnormalities.
  - Type 1 and type 2 diabetes mellitus.
  - Solid organ transplantation.
  - Obesity.
  - Known or suspected obstructive sleep apnea syndrome.
  - Repaired aortic coarctation.
  - Genetic syndromes associated with hypertension (e.g., neurofibromatosis, Turner syndrome, Williams syndrome, or aortic coarctation).
  - Prematurity.

For Medicare members only:

AmeriHealth Caritas considers the use of ambulatory blood pressure monitoring to be medically necessary for patients with suspected white coat hypertension who meet all of the following criteria (Medicare National Coverage Determination 20.19):

- Office blood pressure > 140/90 mm Hg on at least three separate clinic or office visits with two separate measurements made at each visit.
- At least two documented blood pressure measurements taken outside the office that are < 140/90 mm Hg.
- No evidence of end-organ damage.

LIMITATIONS:

All other uses of ambulatory blood pressure monitoring are not medically necessary.
The following quality criteria for ambulatory blood pressure monitoring must be met:

- Monitoring is performed for at least 24 hours.
- Automatic readings are set at ≤ 30-minute intervals.
- Monitoring is performed using a U.S. Food and Drug Administration-approved device that has been validated according to international, standardized protocols prior to use.

Repeat ambulatory blood pressure monitoring may be obtained if the first examination has less than 70 percent of the expected values due to a high number of artifacts.

Routine repeat ambulatory blood pressure monitoring is not clinically proven and, therefore, not medically necessary.

In a circumstance when ambulatory blood pressure monitoring needs to be performed more than once on a patient, the medical necessity and quality criteria described above must be met for each subsequent test.

**ALTERNATIVE COVERED SERVICES:**

- Office or clinic blood pressure measurement.
- Home blood pressure measurement.

**BACKGROUND:**

According to the Centers for Disease Control and Prevention (2016), approximately one of every three adults in the United States has hypertension, and only half of them have their blood pressure under control. Among U.S. children, the prevalence of hypertension is 1.1 percent (Ma, 2016). Primary (essential) hypertension is now identifiable in children and adolescents and is often associated with a positive family history of hypertension or cardiovascular disease, obesity, and lifestyle factors (Flynn, 2017).

Hypertension is classified as follows (systolic/diastolic blood pressure) (Whelton, 2018):

- Normal: < 120 mm Hg/< 80 mm Hg.
- Elevated hypertension: 120 – 139 mm Hg/< 80 mm Hg.
- Stage 1 hypertension: 130 – 139 mm Hg/80 – 89 mm Hg.
- Stage 2 hypertension: ≥ 140 mm Hg/≥ 90 mm Hg.

Accurate blood pressure measurement is essential to correctly classify individuals, ascertain blood pressure-related risk, and guide management. To date, office blood pressure measurements define the relationship between blood pressure and risk, but are subject to fluctuations and phenomena such as white coat hypertension or masked hypertension (Pickering, 2005). Therefore, a diagnosis of white coat hypertension or masked hypertension requires repeated measurements to minimize misclassification of individuals as hypertensive or normotensive (Pickering, 2005).

**Ambulatory blood pressure monitoring:**
Ambulatory blood pressure monitoring is a noninvasive method of obtaining multiple blood pressure readings at regular intervals over a 24-hour (or sometimes 48-hour) period in the person’s own living environment. The rationale for its use within carefully selected populations is to provide more precise and accurate blood pressure data that will lead to improved care management and patient outcomes. The purported clinical advantages are to (Pickering, 2005):

- Detect lower blood pressure (white coat hypertension) or higher blood pressure (masked hypertension) out-of-office compared to in-office measurement.
- Determine the presence or absence of normal nocturnal dipping status (i.e., decreases in an individual’s blood pressure during nighttime hours or when sleeping).
- Assess the adequacy of blood pressure control in persons taking complex antihypertensive medication regimens.
- Provide detailed information on blood pressure patterns in persons with episodic hypertension, chronic kidney disease, diabetes, and autonomic dysfunction.
- Identify persons with apparently refractory hypertension but relatively little to no target organ damage.
- Confirm hypertension in patients in whom there is a large discrepancy between clinic and home blood pressure measurements.

Table 1 in the Appendix illustrates the lack of consensus among guidelines regarding the definition of hypertension in adult populations according to ambulatory blood pressure monitoring. Instead, guidelines use thresholds based on a definition of hypertension (blood pressure >140/90 mm Hg) obtained in an office setting from clinical trials that examined the benefits of treating hypertension. Less robust data exist to support treatment guidelines using ambulatory blood pressure monitoring (Myers, 2011).

In the United States, several ambulatory blood pressure monitoring monitors have been cleared for marketing via the 510(k) process (U.S. Food and Drug Administration, 2019). However, monitors that have not undergone validation testing or U.S. Food and Drug Administration clearance can also be sold in the United States, and few have been formally validated in children (Flynn, 2017).

**FINDINGS:**

For this policy, we included only studies published since 2000 to reflect the most current research in the U.S. context. We included evidence comparing ambulatory blood pressure monitoring to clinic blood pressure measurement or home blood pressure measurement from three randomized controlled trials, multiple cross-sectional studies, and multiple prospective observational studies of generally poor to moderate quality (Health Quality Ontario, 2012; Krakoff, 2006; Lovibond, 2011; Mancia, 2013; National Institute for Health and Care Excellence, 2013; O’Brien, 2013). Heterogeneity in study designs limited comparison of results across studies. No systematic reviews addressed ambulatory blood pressure monitoring in pediatric populations.

There is sufficient evidence to support the safety, efficacy, and cost effectiveness of ambulatory blood pressure monitoring to confirm the presence or absence of white coat hypertension in persons with elevated blood pressure measured by office-based screening. More recent evidence-based guidelines are notably consistent in defining suspected white coat hypertension as > 140/90 mm Hg in the clinic and < 135/85 mm Hg outside the clinic (Canadian
Evidence suggests an association between white coat hypertension and intermediate harmful health outcomes (left ventricular hypertrophy, nephropathy, and retinopathy) in persons with normal blood pressure and persons with sustained hypertension. Therefore, white coat hypertension may not necessarily be a benign condition. Patients with white coat hypertension should be identified for close monitoring and instituting lifestyle improvements early, where necessary. Additional research is needed to better define white coat hypertension and low-risk patients. Insufficient evidence exists to support other routine uses of ambulatory blood pressure monitoring in persons with hypertension.

In 2016, we identified one additional systematic review for the United States Preventive Services Task Force that updated a 2007 systematic review on the benefits and harms of screening for hypertension in adults and summarized evidence on rescreening intervals and diagnostic and predictive accuracy for cardiovascular events of different blood pressure methods (Piper, 2015). The United States Preventive Services Task Force and the Canadian Hypertension Education Program now recommend ambulatory blood pressure monitoring to confirm initially elevated blood pressure measured by office-based screening methods to avoid potential over-diagnosis of isolated clinic hypertension and harms of unnecessary treatment (Cloutier, 2015; Siu, 2015). These results do not change earlier findings; therefore, no changes to the current policy are warranted.

Current guidelines acknowledge the diagnostic superiority of 24-hour ambulatory blood pressure monitoring for its ability to identify sustained hypertension by excluding white coat hypertension, identifying the presence of episodic or masked hypertension, and providing additional prognostic information from nocturnal patterns of blood pressure (Flynn, 2014; O’Brien, 2016). Given the known risks associated with inadequately controlled hypertension, ambulatory blood pressure monitoring may be beneficial when longer measurement periods are needed to diagnose hypertension phenotypes to determine an appropriate diagnosis, and the information would alter care management. There remains a lack of consensus on the best method for identifying individuals who would most likely benefit from ambulatory blood pressure monitoring screening for conditions other than white coat hypertension.

The use of ambulatory blood pressure monitoring for diagnosing masked hypertension warrants further consideration, as a significant portion of untreated and treated persons with non-elevated clinic blood pressure have masked hypertension and abnormal nocturnal blood pressure profiles (Thomas, 2017; Wang, 2017). Masked hypertension and nocturnal blood pressure fall patterns are associated with significantly higher risk of cardiovascular events (Ohkubo, 2005; Salles, 2016). Nocturnal hypertension and non-dipping may be early markers of masked hypertension (Franklin, 2017; O’Brien, 2016).

In 2017, we identified several indices that were developed to identify candidates for ambulatory blood pressure monitoring who have normal office blood pressure, but they require further validation before routine clinical use (Booth, 2016; Schwartz, 2016; Sheppard, 2016). Masked hypertension and masked uncontrolled hypertension are more likely in individuals of African descent, with increased cardiovascular risk and disease states (e.g., diabetes, chronic renal failure, and metabolic syndrome), older persons, males, shortened sleep time, and obstructive sleep apnea (Colantonio, 2017; Franklin, 2017; Thomas, 2017; Wang, 2017). Persons with prehypertension are more likely to have masked hypertension.
hypertension than those with optimal blood pressure and frequently develop target organ damage prior to transitioning to sustained hypertension (Colantonio, 2017; Franklin, 2017).

It is reasonable to apply ambulatory blood pressure monitoring to individuals with normal or elevated (prehypertensive) casual measurements when there is a clinical suspicion of hypertension (e.g., presence of left ventricular hypertrophy) to minimize misclassification of such individuals as normotensive or with controlled hypertension.

In 2018, we added longitudinal data from the Jackson Heart Study (Ravenell, 2017) and updated guidelines from the American Academy of Pediatrics (Flynn, 2017), the American College of Cardiology/American Heart Association (Whelton, 2018), and Canadian Hypertension Education Program (Leung, 2017). Few data have established thresholds for ambulatory hypertension based on U.S. populations. Ravenell et al provides new information derived from an African American population, and both guidelines incorporate updated definitions of ambulatory hypertension while pointing out the need for practitioners to interpret these values in the context of their own patient populations (Leung, 2017; Ravenell, 2017; Whelton, 2018; added to Table 1; Flynn, 2017 in Table 2; see both tables in the Appendix). The guidelines expand the roles for ambulatory blood pressure monitoring, and the policy was modified to reflect these new changes.

In 2019, we added one cost effectiveness analysis to the policy (Beyhaghi, 2019) with no policy changes warranted. The policy ID was changed from CP# 04.01.03 to CCP.1108.

BILLING AND CODING:

Below are National Coverage Determinations, Local Coverage Determinations, and the most commonly submitted codes subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate Centers for Medicare & Medicaid Services references and coding manuals, and bill accordingly.

NATIONAL COVERAGE DETERMINATIONS:

Ambulatory Blood Pressure Monitoring (20.19).

LOCAL COVERAGE DETERMINATIONS:

No Local Coverage Determinations were identified as of the writing of this policy.

COMMONLY SUBMITTED CODES:

<table>
<thead>
<tr>
<th>Codes</th>
<th>Code description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>3074F</td>
<td>Most recent systolic blood pressure less than 130 mm Hg (DM), (HTN, CKD, CAD)</td>
<td></td>
</tr>
<tr>
<td>3075F</td>
<td>Most recent systolic blood pressure 130-139 mm Hg (DM) (HTN, CKD, CAD)</td>
<td></td>
</tr>
<tr>
<td>3077F</td>
<td>Most recent systolic blood pressure greater than or equal to 140</td>
<td></td>
</tr>
<tr>
<td>Codes</td>
<td>Code description</td>
<td>Comments</td>
</tr>
<tr>
<td>-------</td>
<td>-----------------</td>
<td>----------</td>
</tr>
<tr>
<td>mm Hg (HTN, CKD, CAD) (DM)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3078F</td>
<td>Most recent diastolic blood pressure less than 80 mm Hg (HTN, CKD, CAD) (DM)</td>
<td></td>
</tr>
<tr>
<td>3079F</td>
<td>Most recent diastolic blood pressure 80-89 mm Hg (HTN, CKD, CAD) (DM)</td>
<td></td>
</tr>
<tr>
<td>3080F</td>
<td>Most recent diastolic blood pressure greater than or equal to 90 mm Hg (HTN, CKD, CAD) (DM)</td>
<td></td>
</tr>
<tr>
<td>I15.0</td>
<td>Renovascular hypertension</td>
<td></td>
</tr>
<tr>
<td>I15.8</td>
<td>Other secondary hypertension</td>
<td></td>
</tr>
<tr>
<td>N18.</td>
<td>Chronic kidney disease (CKD)</td>
<td></td>
</tr>
<tr>
<td>E10</td>
<td>Type 1 diabetes mellitus</td>
<td></td>
</tr>
<tr>
<td>E11</td>
<td>Type 2 diabetes mellitus</td>
<td></td>
</tr>
<tr>
<td>Z48.2</td>
<td>Encounter for aftercare following organ transplant</td>
<td></td>
</tr>
<tr>
<td>E66.9</td>
<td>Obesity, unspecified</td>
<td></td>
</tr>
<tr>
<td>G47.33</td>
<td>Obstructive sleep apnea (adult) (pediatric)</td>
<td></td>
</tr>
<tr>
<td>Q25.1</td>
<td>Coarctation of aorta</td>
<td></td>
</tr>
<tr>
<td>Q85.0</td>
<td>Neurofibromatosis (nonmalignant)</td>
<td></td>
</tr>
<tr>
<td>Q96</td>
<td>Turner's syndrome</td>
<td></td>
</tr>
<tr>
<td>93784</td>
<td>Ambulatory blood pressure monitoring, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; including recording, scanning analysis, interpretation and report</td>
<td></td>
</tr>
<tr>
<td>93786</td>
<td>Ambulatory blood pressure monitoring, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; recording only</td>
<td></td>
</tr>
<tr>
<td>93788</td>
<td>Ambulatory blood pressure monitoring, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; scanning analysis with report</td>
<td></td>
</tr>
<tr>
<td>93790</td>
<td>Ambulatory blood pressure monitoring, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; review with interpretation and report</td>
<td></td>
</tr>
</tbody>
</table>

**POLICY UPDATES:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Researcher</th>
<th>Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 2, 2019</td>
<td>E. Adams</td>
<td>Added one cost effectiveness analysis with no policy changes. Policy ID changed from CP# 04.01.03 to CCP.1108.</td>
</tr>
<tr>
<td>May 21, 2014</td>
<td>E. Adams</td>
<td>Initial policy.</td>
</tr>
</tbody>
</table>

**REFERENCES:**

On February 11, 2019, we searched PubMed and the databases of the U.K. National Health Services Centre for Reviews and Dissemination, Agency for Healthcare Research and Quality, and Centers for Medicare & Medicaid Services. Search terms were: “blood pressure monitoring, ambulatory” (MeSH), “hypertension/diagnosis” (MeSH), and “ambulatory
blood pressure monitoring.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.


### APPENDIX:

**Table 1. Diagnostic thresholds for hypertension using ambulatory blood pressure monitoring in adults**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>24-hour</td>
<td>≥135/80</td>
<td>&gt;130/80</td>
<td>≥130/80</td>
<td>≥130/80</td>
<td>≥130/80</td>
</tr>
<tr>
<td>Daytime</td>
<td>≥140/85</td>
<td>&gt;135/85</td>
<td>≥135/85</td>
<td>≥135/85</td>
<td>≥135/85</td>
</tr>
<tr>
<td>Nighttime</td>
<td>≥130/75</td>
<td>&gt;120/70</td>
<td></td>
<td></td>
<td>≥120/70</td>
</tr>
</tbody>
</table>


**Table 2. American Academy of Pediatrics updated definitions of pediatric blood pressure categories and stages**

<table>
<thead>
<tr>
<th>Blood pressure</th>
<th>For children ages 1 – 13 years</th>
<th>For children ages ≥13 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt;90th percentile</td>
<td>&lt;120/&lt;80 mm Hg</td>
</tr>
<tr>
<td>Elevated (formerly “prehypertensive”)</td>
<td>≥90th percentile to &lt;95th percentile or 120/80 mm Hg to &lt;95th percentile (whichever is lower)</td>
<td>120 to 129 mm Hg/&lt;80 mm Hg</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>For children ages 1 – 13 years</td>
<td>For children ages ≥13 years</td>
</tr>
<tr>
<td>------------------------</td>
<td>------------------------------------------------------------------------------------------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td><strong>Stage 1 hypertension</strong></td>
<td>≥95th percentile to &lt;95th percentile + 12 mmHg or 130/80 to 139/89 mm Hg (whichever is lower)</td>
<td>130/80 to 139/89 mm Hg</td>
</tr>
<tr>
<td><strong>Stage 2 hypertension</strong></td>
<td>≥95th percentile + 12 mm Hg or ≥140/90 mm Hg (whichever is lower)</td>
<td>≥140/90 mm Hg</td>
</tr>
</tbody>
</table>