PETERSON HEALTH TECHNOLOGY INSTITUTE

Digital Hypertension Management Solutions

HEALTH TECHNOLOGY ASSESSMENT | OCTOBER 2024 | V1.2

PHTI.org

About This Report

The Peterson Health Technology Institute (PHTI) provides independent evaluations of innovative healthcare technologies to improve health and lower costs. Through its rigorous, evidence-based research, PHTI analyzes the clinical benefits and economic impact of digital health solutions, as well as their effects on health equity, privacy, and security.

These evaluations inform decisions for providers, patients, health plans, and investors, accelerating the adoption of high-value technology in healthcare.

PHTI focuses on health technologies designed to replace or augment traditional care delivery, including digital therapeutics, chronic care management apps, and remote patient monitoring technologies.

The Peterson Health Technology Institute

PHTI was founded in 2023 by the Peterson Center on Healthcare, a nonprofit organization dedicated to making higher-quality, more affordable healthcare a reality for all Americans. PHTI and the Center are wholly owned subsidiaries of, and are funded entirely by, the Peter G. Peterson Foundation. PHTI does not accept financial contributions.

PHTI selects assessment topics based on the:

- Burden of disease to the healthcare system;
- Investment and innovation in the digital health technology;
- Body of evidence about the effectiveness of the technology; and
- Stakeholder interest (purchasers, providers, and patients).

PHTI assessments evaluate evidence of the clinical and economic impact of these technologies using the ICER-PHTI Assessment Framework for Digital Health Technologies, which was designed by a team of experts specifically for digital health products and solutions. This is a secondary research review that relies on published literature and information, as well as proprietary data submitted directly from companies. PHTI did not conduct original testing of the products. All companies included in this report were notified and given an opportunity to submit clinical, commercial, and/or economic data, which were included in the evaluation if eligible.

The economic models used in this report are intended to compare clinical outcomes and expected costs at the population level. Model results represent average findings and should not be presumed to represent cost or outcomes for any specific patient or payer.

The findings and recommendations contained within this report represent the opinions of PHTI based on the information considered in this assessment. The findings are current as of the date of publication. Readers should be aware that new evidence may emerge following the publication of this report that could influence the results. Digital hypertension management solutions are likely to evolve over time, which may impact their performance. PHTI may revisit its analyses in updates to this report in the future.

V1.2 was posted on June 8, 2026. It includes a revision to Exhibit 1 to clarify the label of the U.S. adult population with hypertension.

V1.1 was posted on November 26, 2024. It includes a revision to Exhibit 17 to reflect that Cadence does enable data sharing with patient's primary doctor. It also corrects an incorrect citation link (citation 68).

To cite this report, please use the following citation: Peterson Health Technology Institute, "Digital Hypertension Management Solutions," 2024.
https://phti.org/assessment/digital-hypertension-management-solutions/

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At a Glance: Assessment of Digital Hypertension Management Solutions

WHAT IS THE GOAL OF THE TECHNOLOGY?

Digital hypertension management solutions aim to improve patients' self-management and expand access to timely, effective treatment.

WHICH APPROACHES ARE INCLUDED?

Blood Pressure Monitoring | **Medication Management** | **Behavior Change**

WHAT ARE THE CLINICAL BENEFITS?

- **Blood Pressure Monitoring** approaches provide slightly greater, but not clinically meaningful, declines in systolic blood pressure (SBP) compared with usual care, but improvements vary depending on how the care team acts on the data.
- **Medication Management** approaches produce more rapid declines in SBP compared with usual care, which produce clinically meaningful health benefits.
- **Behavior Change** approaches produce limited incremental declines in SBP compared with usual care but may help close access and equity gaps in traditional care models.

WHAT IS THE BUDGET IMPACT?

- Savings from health improvements due to **Blood Pressure Monitoring** approaches are not sufficient to offset the increased net health spending associated with provider reimbursement through remote patient monitoring (RPM)[a] codes at current reimbursement rates.
- **Medication Management** approaches increase net health spending in the initial three-year budget window but have potential to offset and reduce long-term healthcare costs because of savings from avoided cardiovascular events.
- **Behavior Change** solutions have lower prices than the other approaches but the limited incremental improvements in health outcomes are not sufficient to offset the solution price.

WHICH TARGET POPULATIONS COULD BENEFIT MOST?

Digital hypertension management solutions were found to be effective across demographic groups, including age, gender, and rural and urban settings. Studies exclusively focused on diverse and underserved groups found larger hypertension improvements with both digital solutions and usual care.

WHERE ARE THERE OPPORTUNITIES TO OPTIMIZE THESE SOLUTIONS?

Integrate with usual care | Advance the evidence base | Recognize existing financial opportunities | Public financing

[a] Remote patient monitoring (RPM) is the use of digital devices to monitor a patient's health, which may include remote physiological monitoring and remote therapeutic monitoring codes. This report refers to RPM as remote patient monitoring using remote physiological monitoring codes.

Letter From the Executive Director

Hypertension is one of the most widespread and addressable public health crises facing our nation. Yet because the disease often has no symptoms, many patients do not know they have it and may not appreciate how important it is to control. As a result, we continue to lose ground nationally to this silent, yet treatable, killer.

Today, half of all American adults have hypertension, but only one in five have their blood pressure under control. Older women and Black people disproportionately suffer the long-term health effects, including stroke, heart attack, and death. Achieving blood pressure control is complex for both patients and providers within the structure of our healthcare delivery system. High patient volumes, intermittent clinical interactions, and more acute and pressing healthcare needs often result in too few patients receiving the longitudinal care needed to bring blood pressure under control.

However, with the availability of affordable, accurate home blood pressure cuffs and a multitude of effective, often generic, medications, quality treatment for hypertension is within reach. When these elements are appropriately integrated into a patient-clinical workflow, blood pressure can be managed and controlled. The challenge, however, has been delivering these solutions reliably, and effectively, at a national scale.

These circumstances present an opportunity to leverage digital technology to drive better hypertension control across the population. Regular home blood pressure readings help clinicians monitor progress and make necessary adjustments to medication regimens. Data algorithms and digital reminders make it easier to track patients' progress and flag those needing more intense interventions and follow-ups. Virtual care teams can expand clinical capacity, allowing for faster medication titration and adjustments.

The most promising digital solutions featured in this report achieve more meaningful improvements in systolic blood pressure (SBP) than traditional care models. They achieve these gains in SBP more rapidly than usual care, delivering most of their clinical benefits within the first few months.

Yet not all digital hypertension management approaches are equally effective. Solutions that ensure that data from patients is used by care teams to manage medications have superior outcomes. Solutions that primarily target patients' behavior change — including reminding patients to take their medications and encouraging them to improve their diet and exercise — do not deliver incremental health improvements compared to usual care. While some traditionally underserved patients may benefit from the enhanced self-management support these solutions provide, they should not be considered a substitute for clinical care that includes active management of medication regimens.

This report identifies specific digital hypertension management solutions that have the biggest clinical impact. Purchasers should focus on directing resources to these highest-performing interventions and ensure they remain effective as they scale. Policy makers should focus on creating incentives for payers and providers to invest in improving hypertension care through quality programs and innovative payment mechanisms. Together, with focused attention and the help of digital solutions, we can reduce the burden of this highly-treatable disease.

Sincerely,

Caroline Pearson, Executive Director
Peterson Health Technology Institute

Report Contributors and Reviewers

PHTI partners with a diverse set of advisors and stakeholders. Those who directly contributed to this report are listed below. See our website for a full list of partners and advisors, including our Advisory Board and Purchaser Advisory Council, who offer general guidance but do not participate in the assessment process.

Clinical Advisors

The following clinical advisors provided expertise about usual clinical care for hypertension, digital solutions, and primary and secondary health outcomes. The clinical advisors have no conflicts of interest with respect to this assessment.

- Ami Bhatt, MD
  Chief Innovation Officer of American College of Cardiology
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- Daniel B. Kramer, MD, MPH
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Evaluation Partners

The following independent evaluation partners contributed to this report. The evaluation partners have no relevant conflicts of interest to disclose.

- Curta assessed the clinical and economic impact of these technologies, including a systematic literature review and budget impact assessment, using the ICER-PHTI Assessment Framework.
- Charm Economics developed insight into how different technologies work, what they cost to deliver, and their impact on patients and purchasers.
- The Institute for Clinical and Economic Review (ICER) codeveloped the ICER-PHTI Assessment Framework for Digital Health Technologies, and reviewed the framework's implementation in this report.

Other Partners

Manatt Health provided consulting, research, and operational support throughout the development of the report.

Patient Perspectives

PHTI conducted focus groups and interviews with 12 patients with hypertension who had experience with digital hypertension management solutions. Patients were recruited for diversity across age, gender, race and ethnicity, income level, geography, and insurance type.

Company Submissions

PHTI directly engaged companies included in the report and accepted submissions of public and proprietary information to inform the assessment. PHTI did not conduct any primary analysis of patient data. PHTI applied the same standards for minimum evidence requirements and risk of bias reviews to company-submitted information as to all other studies included in the report. Companies did not influence the assessment methods or findings.

Report contributors and reviewers provided important expertise and insight throughout the evaluation process. PHTI is solely responsible for the report and its findings.

Executive Summary

Hypertension, also known as high blood pressure, is one of the most common chronic conditions in the United States, affecting an estimated 120 million adults and growing. It is also a contributing risk factor for potentially fatal diseases, such as heart disease, stroke, and chronic kidney disease. Hypertension affects all demographic groups, with a higher prevalence among Black people, men, and older adults.

Effective hypertension treatment often includes prescription medication, as well as recommended changes to diet and exercise. Patients are typically instructed to monitor their blood pressure at home to produce a series of readings at different times of day. Providers use those blood pressure data to adjust patients' care plan, including making changes to medications and dosage. The process of finding the right combination and dosage of medications can take time and usually requires several visits to the doctor's office, which can be a burden on patients and practices. It can also delay or prevent patients from attaining blood pressure control (BPC).

Digital hypertension management solutions aim to improve patients' self-management and expand access to timely, effective treatment. These solutions are centered around a connected blood pressure cuff that delivers more frequent and reliable home readings. In some solutions, these readings are delivered to care teams, allowing them to track patient progress and make changes to treatment plans. In other instances, the data are used to help patients make recommended behavior and lifestyle changes but are not automatically delivered back to clinicians.

These solutions also take varying approaches to medication management. Some allow patients to track medication adherence but have no direct involvement in prescribing or titration. Other approaches send prescribing recommendations to primary care team members, who may act on the alerts and suggestions. A third approach incorporates a virtual care team that includes a licensed prescriber empowered to adjust the patient's medication directly, with or without consultation with the primary provider.

The solutions reviewed in this report were grouped on the basis of their approach to guiding clinician and patient actions:

1. **Blood Pressure Monitoring** solutions extend existing hypertension care beyond the clinical office by supporting patients' home monitoring and delivering data back to the healthcare provider. Companies with solutions in this approach include AMC Health, Health Recovery Solutions (HRS), and VitalSight (Omron Healthcare).

2. **Medication Management** solutions employ dedicated, virtual care teams to coordinate patients' medication adjustments as a supplement to the patient's main primary care team. Companies with solutions in this approach include Cadence, Ochsner Digital Medicine, and Story Health.

3. **Behavior Change** solutions deliver educational content, alerts, reminders, and virtual interactions with coaches (digital or human) or care teams to improve patient's self-management of their hypertension. Companies with solutions in this approach include DarioHealth, Hello Heart, Lark, Omada Health, and Teladoc Health (Livongo).

This report assesses the clinical effectiveness of these digital hypertension management solutions compared with usual care across 13 different outcome measures, including primary outcomes that focus on reducing systolic blood pressure (SBP) and increasing the proportion of patients achieving BPC. It also estimates the economic impact of these solutions over a three-year budget window. Findings are based on evidence from a systematic literature review and company-submitted information.

Stakeholder Engagement

PHTI solicits input and advice from a diverse set of stakeholders, including health plans, employers, providers, digital health developers, and investors. During the assessment process, PHTI partnered with clinical advisors, experts in health technology assessment, and health economists. PHTI also conducted interviews with 12 patients with hypertension. All companies included in the report were given an opportunity to submit clinical, economic, and other commercial information to inform the assessment; eight of the 11 companies engaged with PHTI during the assessment process, and six submitted evidence for review.

PHTI Assessment Approach

This evaluation has two primary components: clinical effectiveness and economic impact. As described in the ICER-PHTI Assessment Framework for Digital Health Technologies, the evaluation reviews the solutions' clinical effectiveness to understand how they perform on both primary and secondary outcomes of interest, as well as on measures of user experience and health equity. PHTI also conducts a budget impact model to estimate the net impact of the solutions on overall healthcare spending.

Clinical effectiveness: The evidence base was sizable and included many comparative studies with low risk of bias, which provide a clear picture of the clinical findings for digital hypertension management solutions as a whole and by approach. The systematic literature review screened approximately 2,500 pieces of evidence, yielding a total of 73 articles, abstracts, and posters that met inclusion criteria for this assessment.

The primary clinical outcomes for hypertension are focused on blood pressure management and sustained control, including reductions in SBP and increasing the proportion of patients achieving BPC. Minimum clinically important differences (MCID) are reductions in SBP of 5 mm Hg or more compared with usual care. Secondary outcomes — including medication adherence and blood pressure measurement frequency — can play a supportive role in achieving and maintaining hypertension improvements.

Economic impact: The economic analysis was modeled on the basis of the SBP improvements for each approach, as identified in the clinical literature, as well as changes in utilization from the literature. It relies on 10-year estimates of cardiovascular risk based on the Pooled Cohorts Equations (PCE) from the American College of Cardiology (ACC) and American Heart Association (AHA).

The model estimates the number of adults with hypertension who regularly monitor their blood pressure across commercial, Medicare, and Medicaid plans. The model estimates the number of people who could be eligible for digital solutions, the gross reduction in expected healthcare spending resulting from improved BPC for patients enrolled in these programs, and the net impact on health system spending once such savings are offset by spending on the digital hypertension management solutions.

Summary of Findings

Based on PHTI's review of clinical evidence, digital hypertension management solutions that use the **Medication Management** approach deliver clinically meaningful decreases in SBP relative to usual care, and they bring a greater proportion of patients into BPC than usual care. These solutions also support faster improvements in hypertension than what typically occurs under usual care.

Blood Pressure Monitoring: By delivering patient home monitoring data to clinical teams, solutions using the **Blood Pressure Monitoring** approach deliver slightly greater declines in SBP compared with usual care, but improvements do not consistently achieve MCID. The cost savings from these health improvements are not sufficient to offset the increased costs associated with provider reimbursement through remote patient monitoring (RPM) codes at current reimbursement rates.

Medication Management: Creating dedicated care teams to help adjust prescribing, the **Medication Management** approach has the highest quality evidence, showing clinically meaningful improvements in SBP that are achieved more rapidly than with usual care. The review concluded that these solutions increase net health spending in the initial three- year budget window, but — because hypertension risks accrue over the long term — they have the potential to offset costs over a decade because of savings from avoided cardiovascular events.

Behavior Change: Through patient education and coaching, the **Behavior Change** approach provides limited incremental benefit in SBP compared with usual care. By supporting patient hypertension self-management, these solutions may help close access and equity gaps in traditional care models. Our review determined that while the price of these solutions tends to be lower than the other approaches, the small improvements in health outcomes are not enough to offset the added cost of the product.

Based on these results, despite modestly increasing healthcare spending in the short term, **Medication Management** solutions warrant broader adoption, given their ability to provide clinical benefits in hypertension care, potential long-term savings, and improvements to population health. The best opportunity to optimize digital hypertension management may be a combined approach that includes monitoring, medication management, and patient education.

Health Equity: Across the evidence base, studies targeting historically underserved groups — including racial and ethnic minority groups and low-income populations — showed larger declines in SBP across both digital intervention and usual care arms. This suggests that underserved populations can especially benefit from focused hypertension management and that digital solutions may be effective in closing gaps in healthcare access and equity.

PHTI RATINGS BY DIGITAL HYPERTENSION MANAGEMENT APPROACH

● Positive ● Moderate ● Negative
● Higher Clinical Evidence Certainty ○ Lower Clinical Evidence Certainty

Approach	Clinical Effectiveness[a]	Economic Impact	Summary Rating[b]
Blood Pressure Monitoring AMC Health HRS VitalSight	● **Results:** Slightly greater, but not clinically meaningful declines in SBP compared with usual care **Evidence Certainty:** Higher	● Increases net health spending at current RPM reimbursement rates	● **Evidence may support adoption for providers who consistently act on monitoring data**
Medication Management Cadence Ochsner Digital Medicine Story Health	● **Results:** Clinically meaningful and more rapid declines in SBP compared with usual care **Evidence Certainty:** Higher	● Increases net health spending initially, with potential to offset costs over the long-term because of savings from avoided cardiovascular events	● **Evidence supports broader adoption due to clinical benefits, potential long-term savings, and improvements to population health**
Behavior Change Dario Hello Heart Lark Omada Teladoc (Livongo)	○ **Results:** Limited incremental declines in SBP compared with usual care **Evidence Certainty:** Lower	● Increases net health spending because limited health improvements do not offset solution price	● **Current evidence does not support broader adoption for most patients**

Source: PHTI, Digital Hypertension Management Solutions Assessment, October 2024. See PHTI.org for complete report, methods, and recommendations.

Notes: SBP = systolic blood pressure. RPM = remote patient monitoring. [a] Not all solutions have clinical data that meet the inclusion standards for this report. Based on the similarity of approaches, it is fair to assume that companies without solution-specific data perform in line with the category. Purchasers and users will have to make their own assumptions about performance. [b] Summary rating reflects the combination of clinical and economic results.

Next Steps

Given the number of patients with hypertension in the United States, achieving and maintaining hypertension control must be a national priority. Yet, over the past decade, key indicators of hypertension progress have worsened.[1] In this context, digital hypertension management solutions have an important role to play in helping patients lower their blood pressure and improve their long-term cardiovascular health. This outcome depends on improving the clinical impact of digital tools by integrating the best components of existing solutions and aligning payment models with the long-term financial benefits of improved hypertension management.

PHTI's recommendations include:

- Study the effects of combining blood pressure monitoring, goal-driven medication management, and behavior change for improved clinical outcomes and to close access and equity gaps for underserved patient populations.
- Increasingly integrate digital medication management into usual care and into other digital hypertension management solution types.
- Study the long-term impact of digital hypertension management solutions on clinical outcomes and healthcare utilization.
- Encourage greater investment in hypertension management by building short- and long-term budgets in the context of relevant quality improvement programs, such as Medicare Advantage Star Ratings or value-based payment arrangements.

These findings are based on the criteria set forth in the ICER-PHTI Assessment Framework and the currently available evidence. Please see the full PHTI report and appendix for complete assessment, methods, and recommendations.

The Case for Innovation

Affecting nearly half of American adults, hypertension is a silent condition that progressively damages the cardiovascular and related systems.[2] Despite its asymptomatic nature, the risks of uncontrolled hypertension — including heart disease, stroke, and kidney failure — are severe and well-documented. Black Americans have a higher incidence of hypertension than any other group, and Hispanic Americans have the fastest rates of growth in incidence. Effective management of hypertension not only enhances individual health outcomes, particularly among groups that already experience barriers to care, but also holds the potential to significantly reduce national healthcare spending. The number of adults achieving blood pressure control (BPC) in the United States has not kept up with the rising hypertension prevalence, as BPC rates have declined since 2014.[3]

Achieving BPC requires active awareness from both patients and their physicians. Because hypertension often presents no immediate symptoms, more than one in three U.S. adults are unaware that they are experiencing the condition.[4] Lack of awareness can delay diagnosis; prevent timely intervention; and have serious, negative implications for long-term patient outcomes.

Managing hypertension requires frequent adjustments to medication and lifestyle. For those aware of their diagnosis, current usual care includes only periodic check-ups and limited patient engagement between visits, which can be at odds with the dynamic nature of hypertension. Early medication intervention and optimization is often a key part of effective treatment, so if this is not a part of usual care, patient outcomes can suffer. Achieving BPC is the ultimate goal, yet remains elusive for many patients, particularly those who already face barriers accessing care.

Digital hypertension management solutions address different aspects of hypertension management: awareness, treatment, and control. A range of digital hypertension management solutions have come to market, and purchasers — including health plans, employers, and providers — have widely adopted them. By integrating such technology as connected blood pressure monitors, some of the solutions focus on treatment, offering near-real-time tracking and management of blood pressure and empowering both patients and healthcare providers to adjust care to achieve control. Other solutions focus on awareness, predominantly through self-tracking and education. Embracing digital innovation for hypertension management could be essential for advancing hypertension care and achieving significant public health improvements. By enhancing awareness, refining treatment, and improving control, these technologies offer a promising path to better health outcomes and reducing healthcare costs.

This report incorporates scientific evidence, company data, and budget modeling to answer three fundamental questions: **How well do these digital hypertension management solutions work? For whom do they work? Are they worth it?**

Blood pressure control means maintaining a blood pressure level that is considered normal or within a target range.

COMPANIES WITH DIGITAL HYPERTENSION MANAGEMENT SOLUTIONS REVIEWED IN THIS REPORT

AMC Health | Cadence | DarioHealth | Health Recovery Solutions (HRS) | Hello Heart | Lark | Ochsner Digital Medicine | Omada Health | Story Health | Teladoc Health (Livongo) | VitalSight (Omron Healthcare)

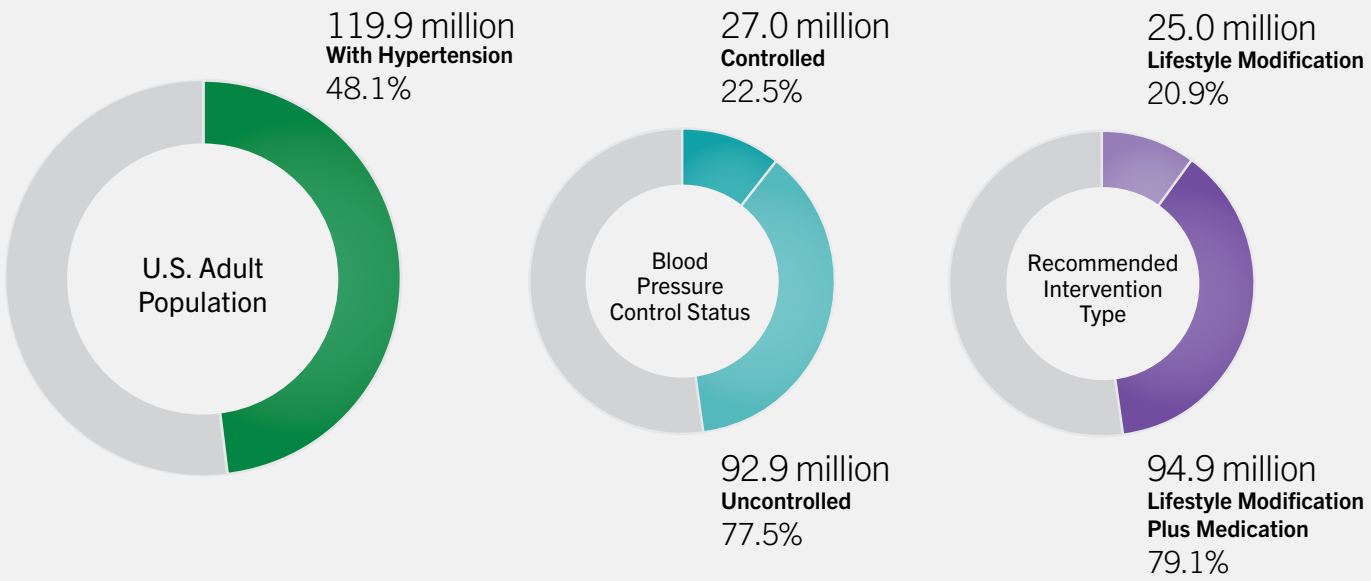
Technology Context

Hypertension, also known as high blood pressure, is a preventable chronic condition that causes progressive damage to the heart and arteries.[5] Known as the "silent killer," hypertension does not always lead to patients experiencing symptoms; more than one in three adults with hypertension do not know they have it.[6,7] Left uncontrolled, hypertension increases the risk of developing other conditions — including heart failure, kidney disease, pregnancy complications, and cognitive decline. Hypertension contributes to more than 685,000 deaths[8] each year and $219 billion in healthcare expenditures.[9] Therefore, increasing patients' awareness of their high blood pressure is a critical first step in reducing the health risks that come with uncontrolled hypertension.

In 2020, the Surgeon General's office issued a national call to action to improve hypertension control in the United States.[10] The numbers — as reported by the Million Hearts initiative — are staggering: 120 million Americans have hypertension, and only 27 million have it under control (see Exhibit 1).[11] Of note, the proportion of U.S. adults with hypertension achieving control had been increasing (1999–2014), but as of 2018, the trend has reversed.[12] The prevalence of hypertension is expected to increase in the coming decades, with disproportionate impact on racially and ethnically diverse communities.[13]

Exhibit 1

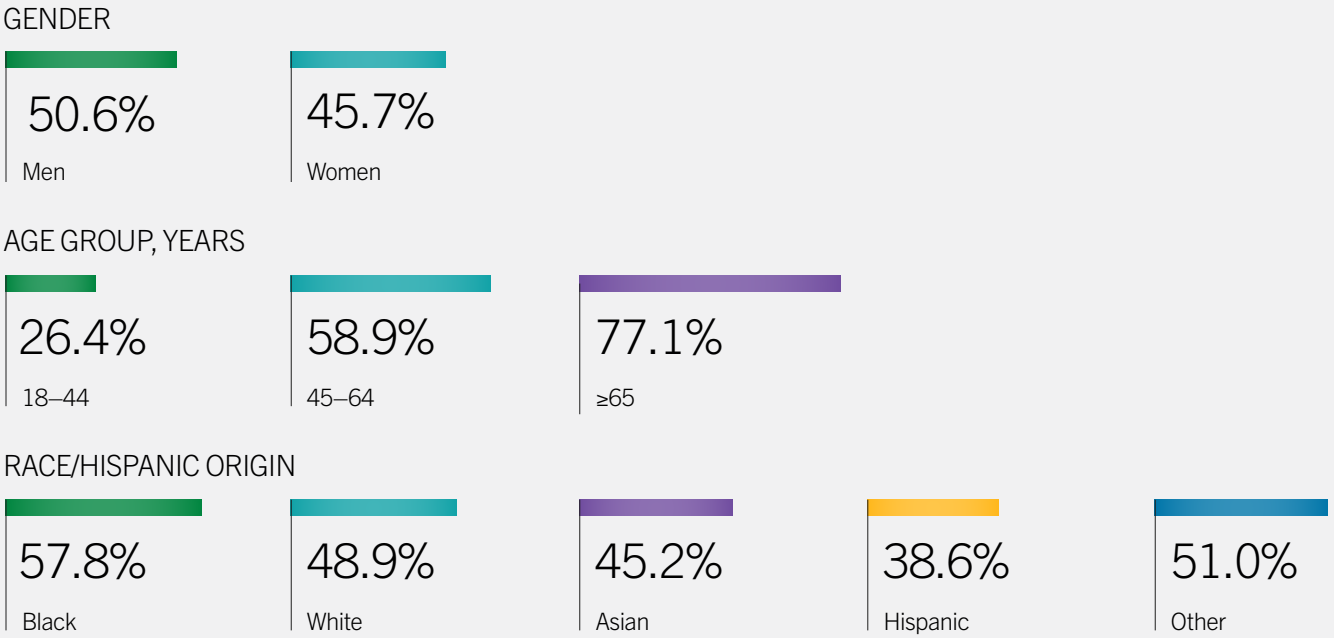
PREVALENCE, CONTROL, AND TREATMENT STATUS OF U.S. ADULTS WITH HYPERTENSION



Source: Million Hearts, "Estimated Hypertension Prevalence,Treatment, and Control Among U.S. Adults," accessed August 16, 2024. https://millionhearts.hhs.gov/data-reports/hypertension-prevalence.html

Exhibit 2

PREVALENCE OF U.S. HYPERTENSION, BY DEMOGRAPHIC GROUP



Source: Million Hearts, "Estimated Hypertension Prevalence, Treatment, and Control Among U.S. Adults: Tables," Table 1, accessed August 16, 2024. https://millionhearts.hhs.gov/files/Estimated-Hypertension-Prevalence-tables-508.pdf

Disproportionate Impacts of Hypertension

Hypertension has a differential impact across demographic groups (see Exhibit 2). Black Americans have the highest rates of hypertension (58%) of any racial or ethnic group, with only 17% in BPC.[14] Prevalence is currently lower among Hispanic populations, but they are projected to experience the largest rate of growth through 2060.[15] Black and Hispanic communities also experience earlier onset of hypertension compared with white adults.[16]

Among women, high blood pressure has historically been underdiagnosed and undertreated,[17] even though women experience elevated risks from pregnancy, menopause, and birth control medication.[18] Prevalence is greater among women at age 60 than among men.[19] Black women, in particular, face significantly elevated risks of developing and experiencing complications of hypertension.[20]

Standard of Care for Hypertension

Once a patient is diagnosed with hypertension, the goal of treatment is to lower their blood pressure to an acceptable range and then maintain it in that range, which is known as "control." Patients work with their primary care physicians and cardiovascular specialists to set care plans and blood pressure targets based on clinical guidelines and individual patient factors, such as trends in blood pressure readings, age, past cardiovascular disease, and the patient's 10-year risk of developing new cardiovascular disease calculated using the ASCVD Risk Estimator Plus from the ACC.[21] The American Medical Association (AMA) also recommends at-home monitoring of blood pressure with a validated blood pressure cuff.[22]

Understanding Blood Pressure

Blood pressure readings are used to diagnose and track hypertension. The results of blood pressure readings are expressed as a fraction of SBP over diastolic blood pressure (DBP), both expressed in millimeters of mercury (mm Hg). SBP in the arteries is measured when the heart is at maximum contraction, while DBP is calculated as the average ambient pressure between contractions.[23] Normal blood pressure is less than 120/80 mm Hg.[24] In the United States, blood pressure consistently measured (two or more independent readings) at 130/80 to 139/89 can be diagnosed as stage 1 hypertension; stage 2 hypertension starts at 140/90[25] (see Exhibit 3).

This report does not include evidence regarding patients with "elevated" blood pressure, which is when the patient's readings fall between normal and stage 1. It also does not consider evidence regarding patients in a hypertensive crisis (blood pressure spikes of 180/120 or greater). Other exclusions include patients with prehypertension or hypertensive disorders of pregnancy.

Management and Treatment of Hypertension

Hypertension is primarily managed with a mixture of lifestyle modifications — such as weight loss, diet, and exercise — and medication, if lifestyle changes are not sufficient. Finding an effective prescription regimen and adhering to that therapy is an important part of lowering blood pressure for most patients with hypertension.[29]

According to the 2017 ACC/AHA Task Force on Clinical Practice Guidelines, patients with stage 1 hypertension and low cardiovascular risk may be managed with lifestyle modifications alone (see Exhibit 4).[30] For patients with stage 2 hypertension, medication is always indicated, along with lifestyle modifications; these patients are typically reassessed monthly until control is reached, and then every 3–6 months thereafter.

Prescribers have many options for treating hypertension. Medications used most often include angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, calcium channel blockers, and diuretics.[31] Patients with uncontrolled stage 2 hypertension often require more than one class of medication to achieve control, though many patients are not prescribed appropriate therapy. An analysis from 2020 found that 40% of patients with uncontrolled stage 2 hypertension were taking a single class of blood pressure medication, while 35% were on two classes, and 17% were on three. Single-dose combination therapies — pills that contain more than one type of antihypertensive medication — can increase the chances of maintaining control but are significantly underutilized.[32]

Appropriate prescribing and dosing of antihypertensive therapy is critical, requiring active involvement by both

Exhibit 3

BLOOD PRESSURE CATEGORIES

	Systolic mm Hg (upper number)		Diastolic mm Hg (lower number)
Normal	Less than 120	and	Less than 80
Elevated	120–129	and	Less than 80
High Blood Pressure (Hypertension) Stage 1	130–139	or	80–89
High Blood Pressure (Hypertension) Stage 2	140 or higher	or	90 or higher
Hypertensive Crisis	Higher than 180	and/or	Higher than 120

Source: American Heart Association, "Understanding Blood Pressure Readings," accessed August 16, 2024. https://www.heart.org/en/health-topics/high-blood-pressure/understanding-blood-pressure-readings.

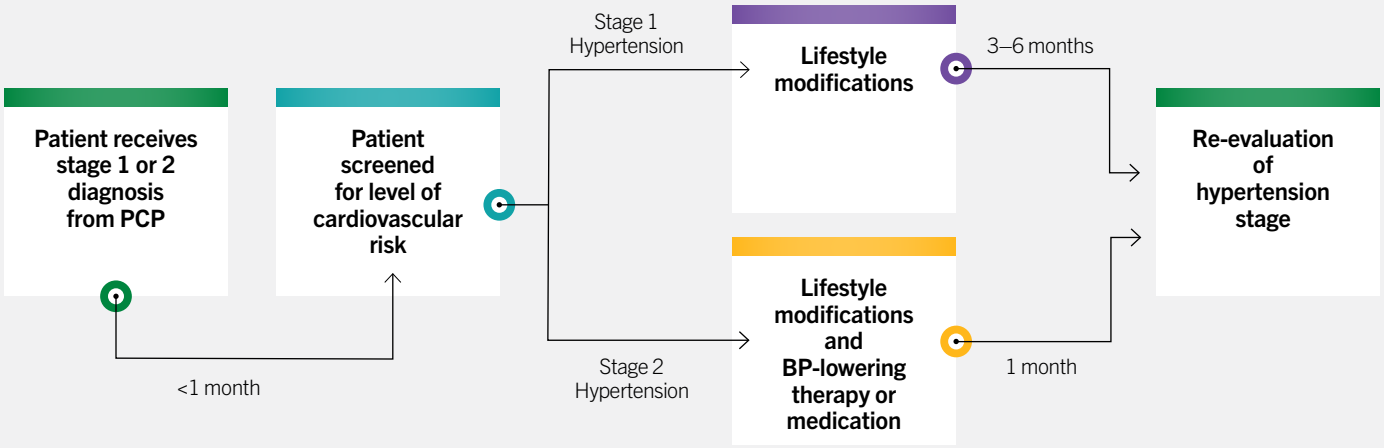
Variation in Blood Pressure Readings

Notable or even significant variation in the results of blood pressure readings can be driven by multiple factors, including the patient's biology, the type of blood pressure monitor used, the time of day, and where readings are taken (e.g., at home or in a doctor's office).[26]

Many patients experience increased blood pressure readings in clinical settings compared with home, known as "white coat hypertension," which can increase office SBP readings by 20 mm Hg higher than home measurements.[27] Conversely, a condition known as "masked hypertension" can result in artificially low readings, which can make diagnosis and treatment challenging.[28]

Exhibit 4

BLOOD PRESSURE THRESHOLDS FOR TREATMENT AND PATIENT FOLLOW UP IN STANDARD CARE



Source: Armstrong, Carrie, "High blood pressure: ACC/AHA releases updated guideline," *American Family Physician* 97, no. 6 (2018): 413–415.

Notes: PCP = primary care physician. Exact pathway might vary based on patient cardiovascular disease (CVD) risk.

patients and providers. Excessive medication can result in hypotension (very low blood pressure), which can cause lightheadedness, fatigue, and falls. To achieve and maintain control, physicians often begin with a low dose of a single medication and increase the number and dosage of medications until control is achieved — a process known as medication titration. For patients, consistent medication adherence is vital. Patients are often instructed to document medications and side effects to discuss with their clinical team during visits. This feedback loop is essential to guide the medication dose adjustment to achieve BPC while minimizing side effects.

Patients with uncontrolled hypertension may engage with a larger care team who may include a primary care physician (PCP), cardiologist, pharmacist, advanced-practice nurse, physician assistant, dietitian, and mental health provider. In particular, the role of nurses and pharmacists in the treatment and management of hypertension has expanded over time.[33,34] A team-based approach can be particularly helpful for medication management, patient follow-up, and self-management support.[35]

Barriers to Access and Care

Diagnosing hypertension and then achieving and maintaining BPC can be challenging for patients and providers, and current treatment patterns often fall short of the standard of care. Despite strong evidence that pharmacologic therapy can be effective in reaching and maintaining control, approximately 51% of adults with hypertension are recommended medication, but are untreated.[37] This statistic is notable because it reflects the state of "usual care" across the country. In the course of usual care, there are many points when the sustained patient and provider focus on hypertension management gets lost.[38]

During this process, busy clinics may have long wait times for office visits, which creates a barrier to making efficient adjustments to medications or titrating the dose of an existing medication. It takes weeks for some medications to have their full effect, so most providers approach BPC gradually, seeking to achieve improvements without causing side effects. Even if patients are prescribed medication, their likelihood of adherence depends on the time spent educating them on when to take their pills, what to do in the case of side effects, and the importance of consistency over time. In addition, more urgent or acute health concerns may take precedence in patients with multiple chronic conditions.

For patients, effective hypertension care often requires adhering to daily

> **"If all team members perform at the highest level . . .**
>
> of their training and licensure, patients with complex health problems and acute concerns can receive the care they need from clinicians with advanced training while other team members support chronic disease management."
>
> — Surgeon General's 2020 Call to Action to Control Hypertension[36]

medication regimens, changing diet and exercise, and frequent doctor visits, as well as careful at-home blood pressure monitoring. Following these care plans can be difficult, and poor health literacy or difficulty accessing care can exacerbate these challenges. Patients with busy lives may simply forget to take their medication or blood pressure readings. People without symptoms may never discover they have high blood pressure if they do not have a regular source of primary care. Taken together, these factors create barriers that can prevent people from initiating care and achieving control.

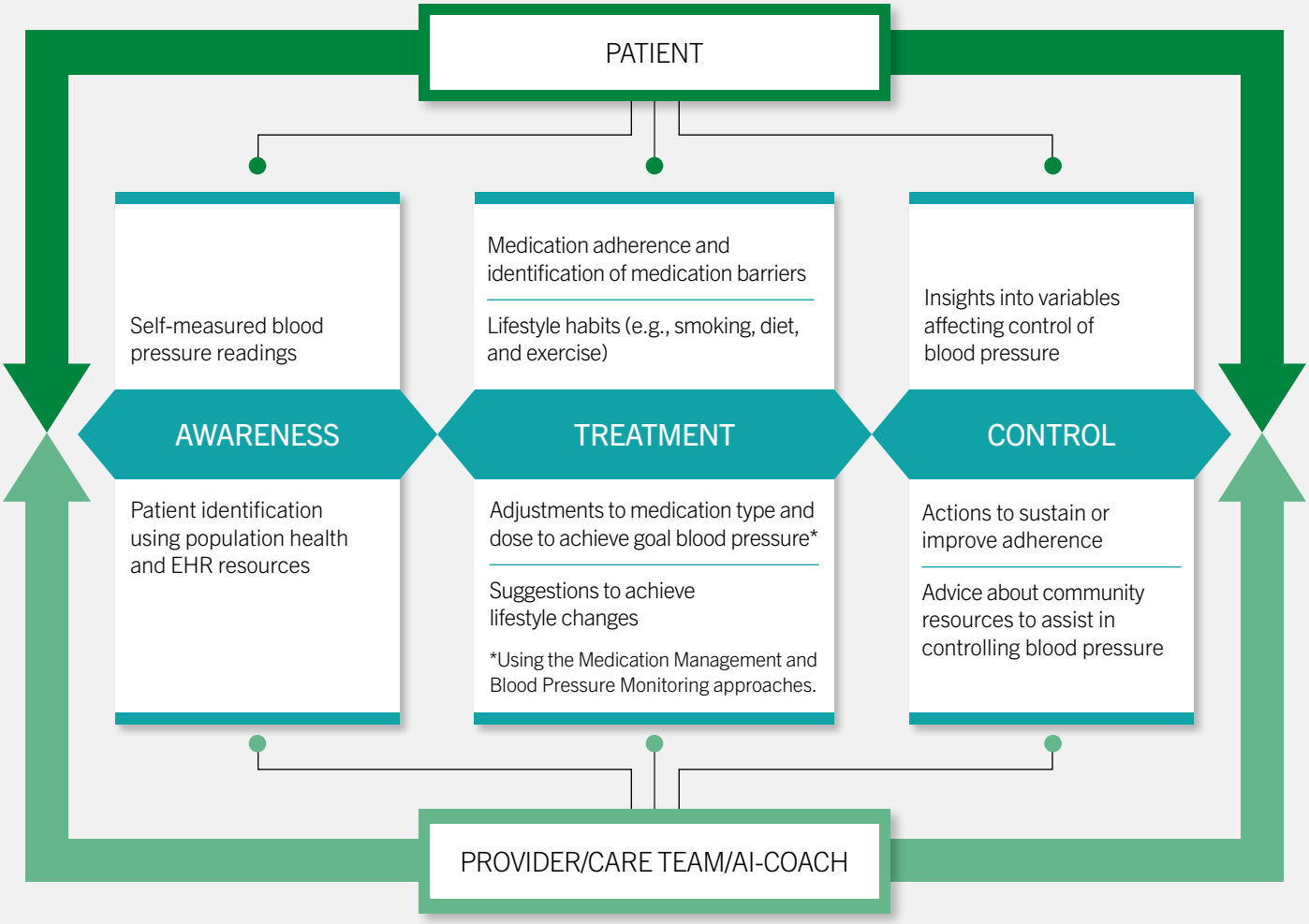
> **"Effective medication management is a critical…**
>
> component of blood pressure monitoring efforts. Scaling this capability to underserved communities at an affordable price is vital to advancing national hypertension goals."
>
> — Dr. Ami Bhatt

Digital Hypertension Management Solutions

Digital hypertension management solutions aim to address the clinical challenges of hypertension by engaging patients in their blood pressure treatment, improving their self-management, and expanding access to timely and appropriate care (see Exhibit 5). Specifically, the solutions in this report seek to: (1) encourage regular blood pressure monitoring using connected blood pressure cuffs, (2) automate data transfer and analysis,

Exhibit 5

OPPORTUNITIES FOR ACTION



(3) support medication management and adjustments, and (4) deliver patient education to encourage behavior change. Some focus on the specific goals of lowering blood pressure and maintaining control, while others target a range of conditions related to hypertension, including general cardiovascular health, obesity, diabetes, and mental health.

At the core of all digital hypertension management solutions is a connected blood pressure monitoring device, which helps patients collect, monitor, and transmit blood pressure readings to guide their hypertension care. Solutions may also include smartphone apps that sync patient data, AI-powered trend analysis, on-demand interactions with health experts, and educational content.

Some solutions send patient data back to clinical care teams to inform medication management and treatment plans. Most medication adjustments for patients using blood pressure monitoring data generally occur within the first four months.[39]

In addition to blood pressure readings, many solutions collect information on medication adherence, physical activity, weight, and diet. These may inform recommendations about self-management habits, address medication side effects, and identify adherence barriers. Most solutions also aim to increase patient engagement through automated medication reminders, personalized feedback, and coaching or nudges based on users' data and health outcomes.

Solutions vary considerably in how they approach the feedback loop between patients and clinicians, and how they support actions taken toward achieving target blood pressure (see Exhibit 6). Key points of differentiation include who receives blood pressure data (i.e., patients, providers, other caregivers, or algorithms) and the actions that they can take based on the information. Some solutions automatically populate data into an existing electronic medical record (EMR) where a care provider can view and act on it. Other solutions act as stand-alone solutions for self-managing hypertension — providing guidance and support for the patient outside of the traditional PCP-patient clinical relationship.

Solutions also take varying approaches to medication management. Some allow patients to track medication adherence but have no direct involvement in prescribing or titration. Other approaches send prescribing recommendations to the primary care team members, who may act on the alerts and suggestions. A third approach incorporates a digital care team with a member who is a licensed prescriber empowered to adjust the patient's medication directly, with or without consultation with the primary provider.

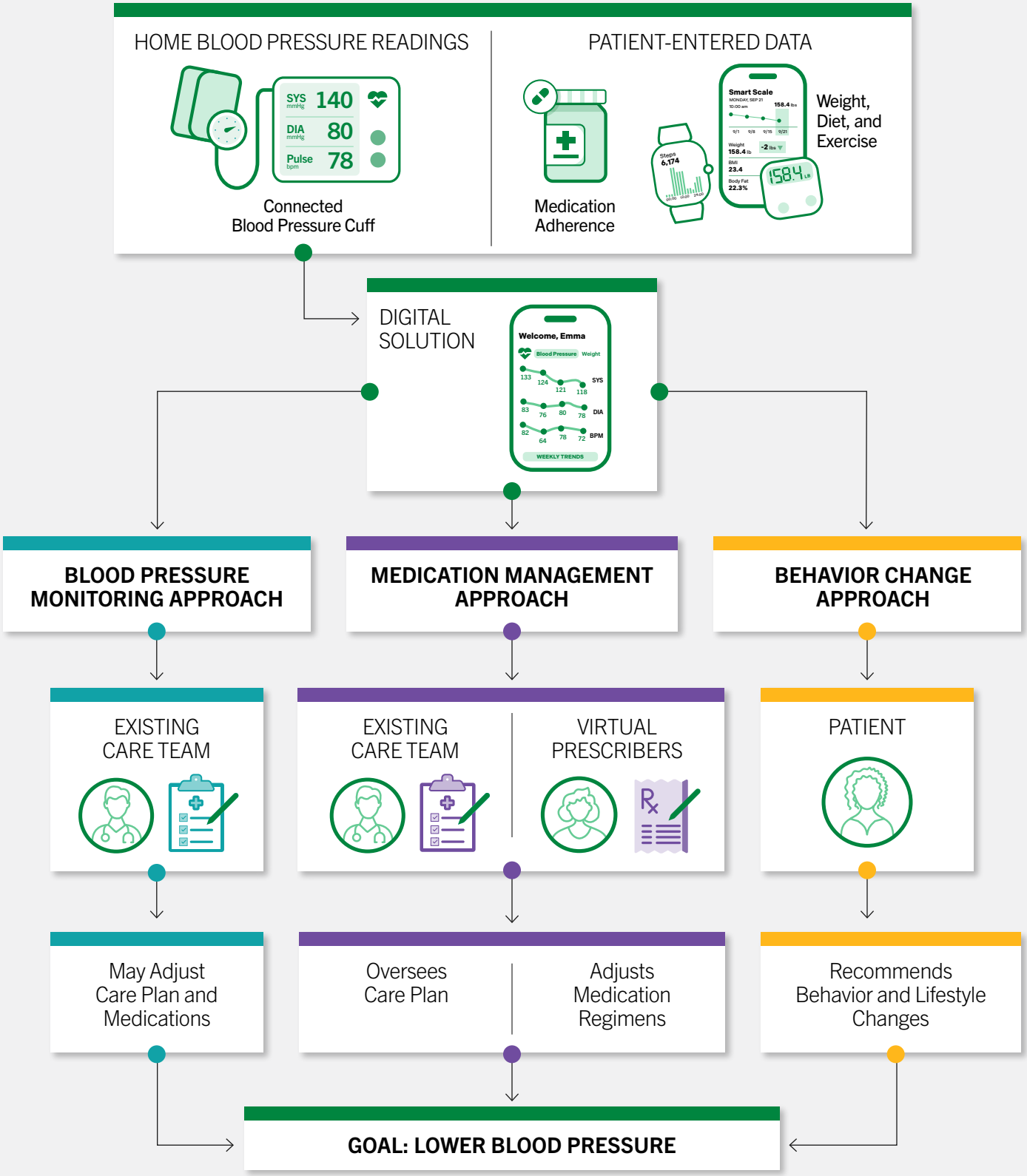
The level of human interaction with the patient also varies greatly among the solutions. Some offer virtual 1:1 appointments with physicians, pharmacists, nurses, dietitians, and coaches; others use only asynchronous communications and synchronous interactions. Most solutions include a blend of synchronous and asynchronous interactions.

Regulation, Validation, Holistic Approach to Evaluation

The U.S. Food and Drug Administration (FDA) regulates medical devices, not programs or platforms.[40] The agency is responsible for regulating blood pressure cuffs and "software as a medical device" products. In most cases, the FDA clears new blood pressure monitors through the 510(k) premarket notification review process[41] for low- and moderate-risk devices, which is designed to ensure new devices work at least as well as previously approved predicate devices. FDA-cleared blood pressure devices are also assessed using the AMA's Validated Device Listing Criteria.[42–44] The criteria for a monitor to be deemed validated include FDA clearance, independent third-party testing under an accepted international protocol, and having appropriate cuff sizes for the general population. More than 90 devices are now listed in the U.S. Blood Pressure Validated Device Listing (VDL™), established by the AMA.[45] STRIDE BP and Medaval are nonprofit organizations that also provide guidance and list validated blood pressure measuring devices for purchasers. This report is focused holistically on the digital hypertension management solution, including the patient-facing smartphone application, AI models, live and asynchronous interactions, educational resources, and personalized alerts and reminders. The report does not evaluate the performance of any of the blood pressure monitoring devices themselves.

Exhibit 6

HOW DIGITAL HYPERTENSION MANAGEMENT SOLUTIONS WORK



> **"While traditional hypertension management programs are failing most populations…**
>
> digital health solutions hold the promise of better cardiovascular health for millions. If done right, digital hypertension tools could enhance patient engagement, intensify treatment and medication adherence, and optimize blood pressure control on a large scale."
>
> — Dr. Naomi D.L. Fisher

Three Approaches to Digital Hypertension Management

Digital hypertension management solutions leveraging a connected blood pressure monitor aim to improve the feedback loop between patients and providers to manage and control the patient's hypertension. The report assumes patients are receiving some form of usual care and seeks to understand the clinical impact of the solutions beyond usual care. This report assesses 11 digital hypertension management solutions, which can be grouped into three broad approaches to hypertension care.

Blood Pressure Monitoring solutions extend existing hypertension care beyond the clinical office by supporting patients' home monitoring and delivering data back to the healthcare provider.

These solutions primarily focus on facilitating the exchange of blood pressure monitoring information between patients and their primary providers. They supplement periodic, in-office blood pressure measurements with frequent at-home readings from a connected blood pressure cuff that transmits results electronically back to the provider. These solutions integrate with electronic health records (EHRs) to directly upload patient-collected data. The frequency of information transmission, who receives the information (e.g., doctor, nurse, team pharmacist), and the thresholds for alerts can be customized. Once blood pressure data are in the hands of the primary provider, it is up to them to monitor and act upon the information. Providers typically purchase these digital solutions and then get reimbursed by insurance when they bill the remote patient monitoring (RPM) codes.

Companies with solutions in this approach include AMC Health, HRS, and VitalSight.

Medication Management solutions employ dedicated, virtual care teams to coordinate patients' medication adjustments as a supplement to the patient's main primary care team.

These solutions build on the blood pressure monitoring solutions by adding a specific focus on medication management. They use virtual care teams — which include a licensed prescriber and may include licensed physicians, pharmacists, nurses, and health coaches — to monitor patient data and adjust medication therapy (i.e., change prescription drugs and dosing). These solutions are designed to supplement — not replace — the patient's primary care provider or cardiologist by providing access to teams who can take an active approach to titrating medications between visits. Some of these solutions may enable RPM billing for providers to receive reimbursement from insurance plans.

Companies with solutions in this approach include Cadence, Ochsner Digital Medicine, and Story Health.

Behavior Change solutions deliver educational content, alerts, reminders, and virtual interactions with coaches (digital or human) or care teams to improve patient's self-management of their hypertension.

These solutions focus on enabling better patient self-management through education, coaching, support, and reminders. They analyze blood pressure readings from a connected device to prompt in-app interactions with live, asynchronous, and automated messaging and educational content. These interactions focus on encouraging healthy lifestyle choices, such as diet and exercise, and on educating patients on effective hypertension self-management, including a significant focus on medication adherence. These solutions may target conditions beyond hypertension (e.g., cardiovascular care, weight loss, diet) as well. This approach does not typically deliver blood pressure readings back to providers' offices and is generally not integrated with patient-PCP workflows or medication management teams.

Companies with solutions in this approach include Dario, Hello Heart, Lark, Omada, and Teladoc (Livongo).

How the Solutions Were Selected for Assessment

The solutions in this assessment were identified through a multistep market analysis. Products were initially identified through a scan of the digital hypertension management solutions space using multiple market analysis platforms and published literature. A company-by-company analysis examined eligible products and grouped those with similar characteristics, claims, customers, and mechanisms of action. The final list of solutions was informed by the results of company meetings, company-submitted data, detailed company research, and input from stakeholders, including health plans, employers, providers, and virtual health experts.

Minimum Criteria for Inclusion

All of the solutions included in this report:

- Are sold by companies that have clinical evidence of treating hypertension or indicate they target people with hypertension;
- Offer hypertension-specific modules and care-escalation pathways, either as a stand-alone solution or as part of a larger offering;
- Connect to a blood pressure monitor that transmits patient data;
- Are sold in the United States;
- Are sold either to payers directly or to providers who are then reimbursed by payers.
- Meet one of two financial requirements (see Exhibit 7):
  - They are sold by companies that are publicly traded or have raised at least $25 million in private funding, or
  - They are developed by a health system and have been sold through at least one external purchase.
- And are part of an active care plan, evidenced by meeting two criteria:
  - They are recommended or prescribed following hypertension diagnosis by a healthcare professional; and
  - They are intended to be used to manage hypertension with a live case manager, such as a doctor, nurse, or coach, or are used for clinically-driven patient self-management with algorithm-driven recommendations.

Exhibit 7

COMPANY HISTORY AND FUNDING

Company	Year Founded	Ownership	Total Private Investment /Market Cap[a]
BLOOD PRESSURE MONITORING			
AMC Health	2002	PRIVATE	$25M
HRS	2012	PRIVATE	$85M
VitalSight	1933	PUBLIC	$9.3B
MEDICATION MANAGEMENT			
Cadence	2020	PRIVATE	$143M
Ochsner Digital Medicine	2015	NOT-FOR-PROFIT	N/A
Story Health	2020	PRIVATE	$27M
BEHAVIOR CHANGE			
Dario	2011	PUBLIC	$32M
Hello Heart	2013	PRIVATE	$145M
Lark	2011	PRIVATE	$210M
Omada	2011	PRIVATE	$530M
Teladoc (Livongo)	2008	PUBLIC[b]	$1.5B

Source: PitchBook Data, Inc.

Notes: [a] Market cap for public companies, as of September 30, 2024. [b] Acquired by Teladoc in 2020 for $18.5 billion.

Privacy and Security

Payers and providers continue to emphasize the critical importance of privacy and security when making digital health purchasing decisions. Many digital hypertension management solutions share blood pressure monitoring and other patient-reported data with providers through their EHR systems. These integration points create potential security risks that should be carefully evaluated prior to selecting a solution vendor. Many hypertension solution providers work with purchasers to access qualified lists of patients or employees. These lists may be identified using personal health information or claims filed for relevant diagnosis codes. Once patients are using these platforms, they may be unaware of what information may be stored or reviewed by the solution, including visual information or recordings. Even if a platform does not actively record sessions, user agreements may enable them to start doing so at any time. Based on their IT setup and specific solution configuration, purchasers should conduct a thorough analysis of privacy and security protections prior to implementation.

Patient Perspectives

Managing hypertension is an onerous task for patients. It requires them to track blood pressure measurements — often multiple times a day — to determine whether their blood pressure is under control. To maintain control, many patients must take daily medications and make recommended lifestyle changes, including diet and exercise. Some patients track their blood pressure measurements manually and report them to their doctor, while others use digital solutions to monitor their hypertension, including smart watches, consumer apps, and physician- and health plan–provided tools.

Patient Self-Monitoring with Digital Solutions

Patients reported that virtual hypertension management solutions provide them with more real-time data and trend analysis that helps them manage their care and know when to engage their healthcare providers.

> **"Blood pressure is a silent killer,**
> and for that reason, it's good to monitor it. Blood pressure can get so high and other things happen to your body. That's why it's so helpful to use your [digital] tools to see where your body is at."
>
> — Focus Group Participant

> **"I just can't keep up with all the readings.**
> I'm setting alarms to remind me to take them, but I get distracted by so much stuff that's happening. On top of just everyday life, it's a lot."
>
> — Patient Interview Participant

Sharing Information with Clinicians

Patients emphasize the importance of being able to share blood pressure readings with their doctors and to contact a member of their care team when they have questions or concerns. They reported that digital tools made it easier to get questions answered without visiting the office.

> **"If I take a reading, and it's high,**
> I'll communicate with my doctor, and they tell me to take another reading in an hour, or they will tell me to take a reading in the morning. These tools are absolutely saving me a trip to the doctor."
>
> — Focus Group Participant

> **"I think the medical profession appreciates the tools…**
> because it keeps their offices not as busy, so they can take care of the people who really need to be seen."
>
> — Focus Group Participant

Medication Management

Patients reported that digital solutions help them manage their medications and track their symptoms. Patients expressed that these tools help them remember to take their medications at the right time and allow them to keep track of the medications' effects on their blood pressure.

> **"Today, I took a medication…**
> that made my blood pressure very low. I had to come home and lie down. The [digital] tool will track this"
>
> — Focus Group Participant

> **"Your blood pressure can spike for a million reasons.**
> Taking it at a single point in time is useless. With the [digital] tools, you can see trends. If the trend is normal, then OK, don't bother. But if I am trending up, then maybe I should talk to the doctor, or maybe I need to switch meds."
>
> — Focus Group Participant

Clinical Effectiveness

This report evaluates the effectiveness of digital hypertension management solutions across clinically important health outcomes data, as well as evidence pertaining to health equity and user experiences based on a systematic literature review.

The primary clinical outcomes for hypertension are focused on blood pressure management and sustained control, aiming for clinically meaningful reductions of more than 5 mm Hg in SBP compared with usual care. Secondary outcomes, including medication adherence, can play a supportive role in achieving and maintaining these improvements in primary hypertension outcomes. User experience metrics are important indicators of patient engagement with the solutions, and health equity results demonstrate the ability of digital hypertension management solutions to improve care for underserved populations.

The systematic literature review identified a substantial body of evidence, including several randomized controlled trials. Most studies include 6–12 months of data. Detailed clinical methods and findings are described below.

Systematic Literature Review

Using the methods described in the ICER-PHTI Assessment Framework, the systematic literature review included published and unpublished evidence on clinical effectiveness from three data sources: online databases and conference proceedings, company-provided data, and company websites. Independent reviewers conducted the systematic review of published scientific literature, gray literature, online databases, and conference proceedings on the basis of the predefined inclusion/exclusion criteria in Exhibit 8 (Prospero Registry). PHTI also distributed a data request to each company included in the evaluation, and their submissions were reviewed according to the same criteria. See **Appendix A** for a detailed methodology.

Exhibit 8

PICOTS INCLUSION AND EXCLUSION CRITERIA

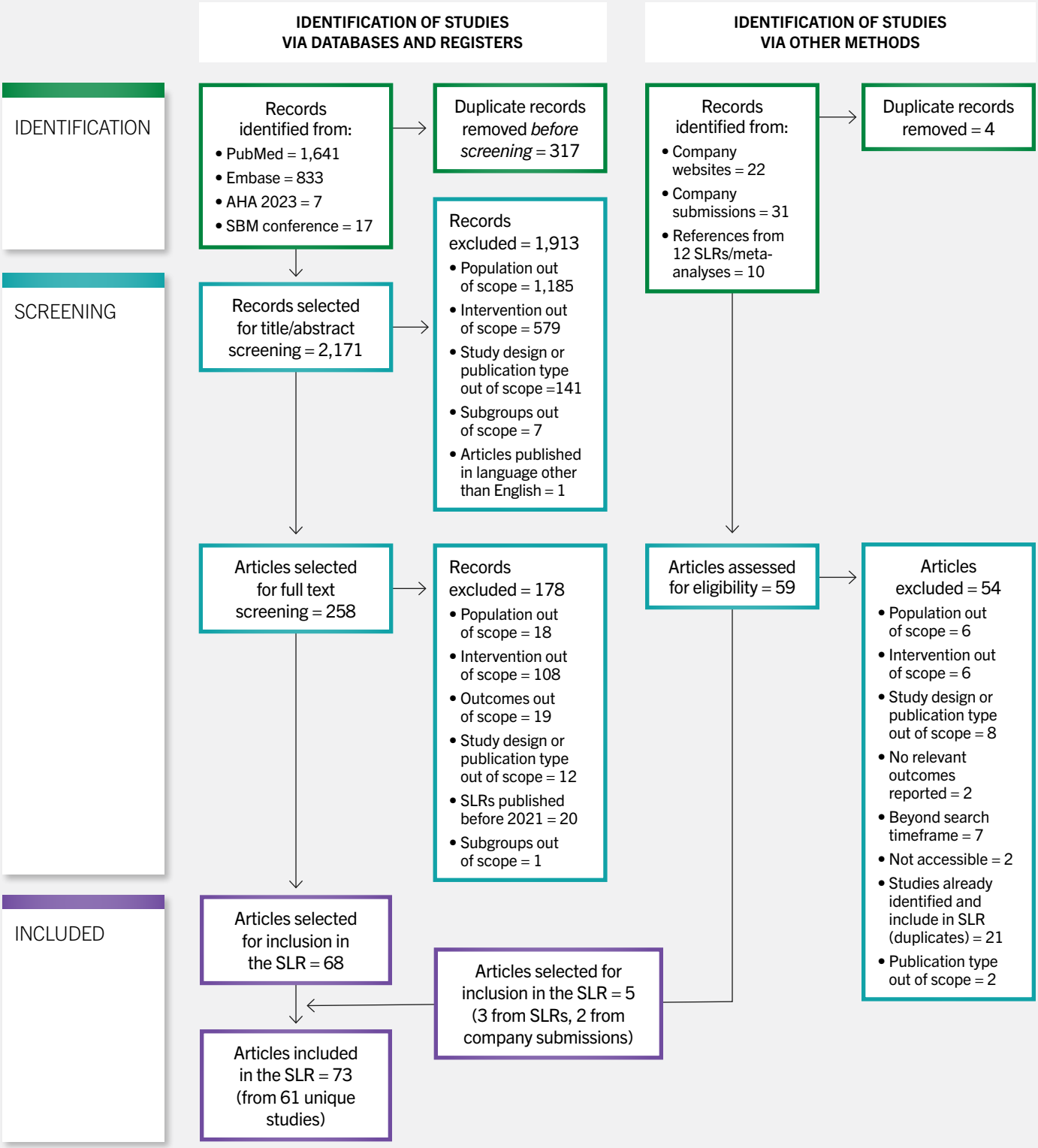
Criteria	Exclusion Criteria
POPULATION: Adult patients with hypertension[a]	Patients with prehypertension or elevated blood pressure Pregnant women with gestational hypertension
SUBGROUP: Age; comorbid conditions, including type 2 diabetes, cardiovascular disease, chronic kidney disease, and/or hyperlipidemia (based on data availability)	
INTERVENTIONS: Connected blood pressure monitors with a cuff linked via personal area network interface[b] to disease management support by: • a case manager[c] • artificial intelligence only[d] (as a part of active care plan[e])	Cuffless blood pressure monitors Telehealth without connected device, and/or personal area network interface that are not approved or available in the United States
COMPARATORS: Usual care via: • traditional patient blood pressure measurements at the clinical setting • unconnected home blood pressure monitoring	N/A
OUTCOMES: See Exhibit 11	N/A
STUDY DESIGN: Clinical trials (randomized, nonrandomized, or single arm) and observational studies of any sample size and SLRs[f]	Editorials, commentaries, study protocols, reviews, and case reports
LANGUAGE: English	N/A
DATABASES: EMBASE and MEDLINE (via PubMed)[g]	N/A
CONFERENCES: American College of Cardiology, American Heart Association, Society of General Internal Medicine, and Society of Behavioral Medicine	N/A
DATE OF PUBLICATION: Databases: 2014–2024 and Conferences: 2021–2024	N/A
GEOGRAPHY: United States	N/A

Notes: N/A = not applicable. SLRs = systematic literature reviews.

[a] Defined per AHA/ACC blood pressure guidelines as SBP ≥130 mm Hg and diastolic blood pressure as ≥80 mm Hg (Whelton 2018). [b] Including Bluetooth, Wi-Fi, NFC, or ZigBee. [c] Defined as a PCP; nurse; pharmacist; licensed medical professional; or nonmedical case manager, including a hypertension specialist or coach who is a part of the care or intervention team. [d] Automatic responses based on interpretive algorithms. [e] Must be recommended or prescribed as a result of a diagnosis of a clinical condition. [f] SLRs were not extracted for data and were utilized only for manual reference screening. [g] Targeted search for company-specific studies.

Exhibit 9

PRISMA DIAGRAM OF CLINICAL EVIDENCE



Notes: Systematic literature review (SLR) was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Articles include peer-reviewed publications, and conference abstracts and posters.

The search of online databases and conference proceedings identified 2,498 pieces of evidence (records). Reviewers screened these records for inclusion and identified 68 eligible articles (including peer-reviewed journal publications and conference posters/abstracts) and 12 systematic literature reviews/meta-analyses. Ten references from the systematic literature reviews/meta-analyses were reviewed for potentially relevant articles, resulting in three additional eligible articles included in this assessment. Reviewers screened articles submitted by the companies included in this report or identified on their websites: six companies (AMC Health, Cadence, Hello Heart, Ochsner Digital Medicine, Omada, and Teladoc (Livongo)) submitted 31 clinical articles for review; searches of websites from companies included in this assessment identified 22 articles. After screening these 53 articles using the PICOTS criteria, two more articles were added to this literature review, for a total of 73 articles from 61 unique studies (see Exhibit 9 on prior page).

Altogether, the body of evidence for this systematic literature review included 20 articles based on results from randomized controlled trials, one article based on a nonrandomized controlled trial, 12 articles based on comparative observational studies, and 40 articles based on single-arm observational studies. The included articles are listed in **Appendix B-1;** see **Appendix B-2** for a list of all company-specific evidence that did not meet inclusion criteria.

Evidence Requirements and Risk of Bias

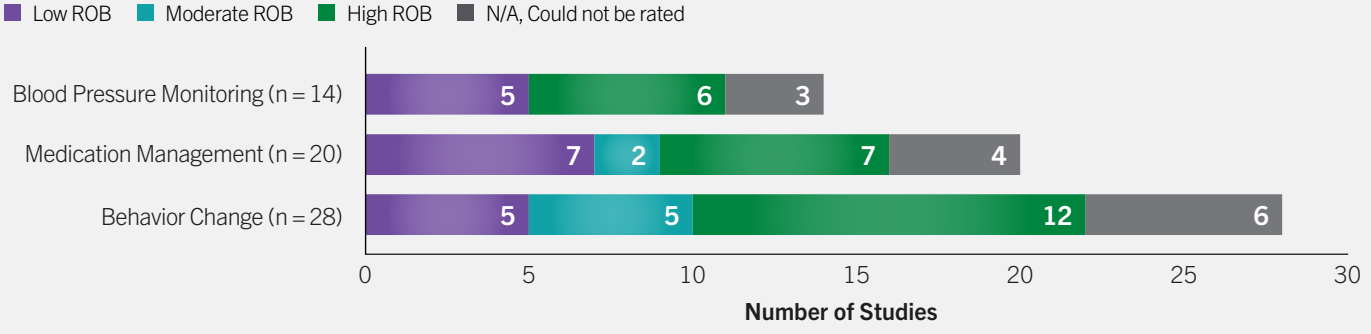
According to the ICER-PHTI Assessment Framework for Digital Health Technologies, the digital health interventions in this report qualify as Tier 3a because they are professionally directed therapeutic services used in consultation with a medical professional. While not all digital solutions in this report have clinician involvement in their offering, they are intended to treat a clinical condition (i.e., hypertension) that is diagnosed by a healthcare professional. PHTI considers all relevant evidence that meets the PICOTS criteria in Exhibit 8 including real-world evidence from single-arm studies. PHTI prioritizes evidence meeting the minimum standards for Tier 3, which includes high-quality observational or quasi-experimental studies with appropriate comparators. The best evidence would be a randomized controlled trial.

Independent reviewers conducted evidence quality assessments, or risk of bias ratings, on 48 of 61 studies with sufficient detail to rate. Details on the rating methods for the risk of bias ratings are provided in detail in **Appendix A.** The 14 randomized controlled trials were rated with the Cochrane Collaboration Risk of Bias in Randomized Trials Version 2 (RoB2) and four studies were rated with low, five studies with moderate, and five studies with high risk of bias. The 34 nonrandomized studies (eight comparative observational studies and 26 single-arm studies) were rated with the Newcastle-Ottawa Scale (NOS). The 61 unique studies in the systematic literature review were mapped to approaches on the basis of the design of their intervention arm, and then grouped into the three specific approaches to digital hypertension care: **Blood Pressure Monitoring, Medication Management,** and **Behavior Change.**

The number of studies for each approach by risk of bias ratings is shown in Exhibit 10. Details on the risk of bias ratings for each study are shown in **Appendix C.**

Exhibit 10

RISK OF BIAS (ROB) RATINGS FOR CLINICAL STUDIES BY APPROACH



Notes: ROB = risk of bias. N/A = not applicable. Maciejewski 2014 is counted twice — in both the Medication Management and Behavior Change approach — increasing the total clinical count in this exhibit to 62. For ease of interpretation across risk of bias ratings, "Low" refers to original ratings of "Low Risk of Bias" (RoB2) or "Good Study Quality" (NOS), "Moderate" refers to original ratings of "Some Risk of Bias" (RoB2) or "Fair Study Quality" (NOS), and "High" refers to original ratings of "High Risk of Bias" (RoB2) or "Poor Study Quality" (NOS).

Compared with past PHTI reports on type 2 diabetes and musculoskeletal care, the evidence base for digital hypertension management solutions was larger and more robust. It included more comparative and low risk of bias studies, which inform the clinical findings for digital hypertension solutions as a whole and by approach.

Hypertension Clinical Outcomes

This evaluation reviewed evidence across 13 outcome measures (see Exhibit 11). Primary outcome measures focused on reducing SBP and increasing the proportion of patients achieving BPC, compared with usual care, both of which are core goals of hypertension care and guide treatment plans and medication management.

Clinically, SBP (the blood pressure when the heart contracts) is used to guide medication adjustments until a patient is in BPC range. Providers adjust medications and dosage to bring down patients' blood pressure. They also rely on patients to communicate medication side effects, such as hypotensive episodes that can lead to lightheadedness or dizziness.[46] Ideally, patients should achieve BPC, which means sustaining blood pressure under 130/80 mm Hg or the recommended levels based on age and health status (e.g., comorbidities like frailty).

Secondary outcomes included a range of clinical measures, such as frequency of blood pressure monitoring and medication adherence. These outcomes measure aspects of patient self-management and may support improvements in primary outcome measures.

To establish an agreed-upon level of difference that would be "clinically meaningful" in the context of treatment plans, prognosis, complications, and patient quality of life, clinicians and standards bodies often define a "minimal clinically important difference" (MCID) for important measures. As per expert input from Clinical Advisors, in the hypertension context, interventions that reduce systolic blood pressure levels by 5 mm Hg or greater than usual care are considered to meet MCID.

Exhibit 11

DETAILED SUMMARY OF CLINICAL, USER EXPERIENCE, AND HEALTH EQUITY OUTCOMES

Primary Clinical Outcomes	Secondary Clinical Outcomes	User Experience and Health Equity Outcomes
SBP CHANGE • SBP change over time (mm Hg) • Between-group differences in SBP change over time • Between-group differences in SBP at follow-up times	BP MEASUREMENT FREQUENCY • Average number of BP measurements during a given period (e.g., per day, per month, or across the study duration) • Number of patients who transmitted a certain amount of BP measurements during the study • Total number of months with a certain number of transmitted BP measurements	ENGAGEMENT • Adherence to video visits • Number of coaching conversations/interactions • Number of peer-group interactions • Number of lessons completed • Proportion (%) of patients completing ≥1 self-monitoring activity per day
BPC • Proportion (%) of patients achieving BPC	MEDICATION ADHERENCE • Pharmacist-reported patient as ≥80% adherent • Proportion of days covered over 12 months • Self-reported medication adherence scales (e.g., Morisky Medication Adherence Scale, Hill-Bone Medication Adherence Scale) • Patients categorized as having "no missed doses" vs. "any missed doses"	USER EXPERIENCE
	MEDICATION INTENSITY • Number of medications prescriptions at study entry • Number of changes (increases/decreases) in the number of medications prescribed to patient over study duration • Total number of medications at study close	USER SATISFACTION
	DBP[a]	RETENTION
	MAP[a]	HEALTH EQUITY • Access • Accessibility • Distribution
	SAFETY (ADVERSE EVENTS)	

Notes: SBP = systolic blood pressure. BPC = blood pressure control. BP = blood pressure. DBP = diastolic blood pressure. MAP = mean arterial pressure.

[a] DBP and MAP outcomes were excluded from this evaluation based on expert input from clinical advisors and limited data in the SLR evidence.

Primary Clinical Outcomes

The primary outcomes for managing hypertension are change in SBP and BPC. Fifteen studies compared the change in SBP using a digital hypertension intervention with usual care and 32 single-arm studies examined SBP improvements with digital solutions (See **Appendix D** for comparator studies and **Appendix F** for single-arm studies).* For BPC, 12 studies compared a digital hypertension intervention with usual care and 16 studies examined digital hypertension interventions alone (see **Appendix E** for comparator studies and **Appendix G** for single-arm studies).

Hypertension Control Under Usual Care

The assessment prioritizes evidence from clinical studies with comparators over single-arm studies to understand the incremental impact of digital interventions relative to usual care for lowering high blood pressure. Usual care is a heterogeneous set of clinical treatments and patients' self-management between office visits. While standard of care represents optimal treatment, usual care may vary because of numerous real-world challenges, including patients' ability to consistently follow their treatment plan, take medications, and make lifestyle changes. Providers' treatment may also vary from standard of care because of staffing limitations, competing clinical priorities, or poor follow-up.

Comparative studies in this evaluation include a range of usual care approaches, which may include home blood pressure monitoring and patient education, in addition to traditional in-office care. Prior research has shown that usual care for hypertension produces small reductions in SBP with substantial variation across patients. A systematic review and meta-analysis of 28 studies from the United States found an average 3.9 mm Hg SBP reduction in the control group after 12 months.[47] The Sprint Trial, which included 9,361 adults from 102 clinical sites from the United States showed a 1.6 mm Hg SBP decrease from baseline after three years follow up in usual care.[48]

Primary Outcomes by Approach

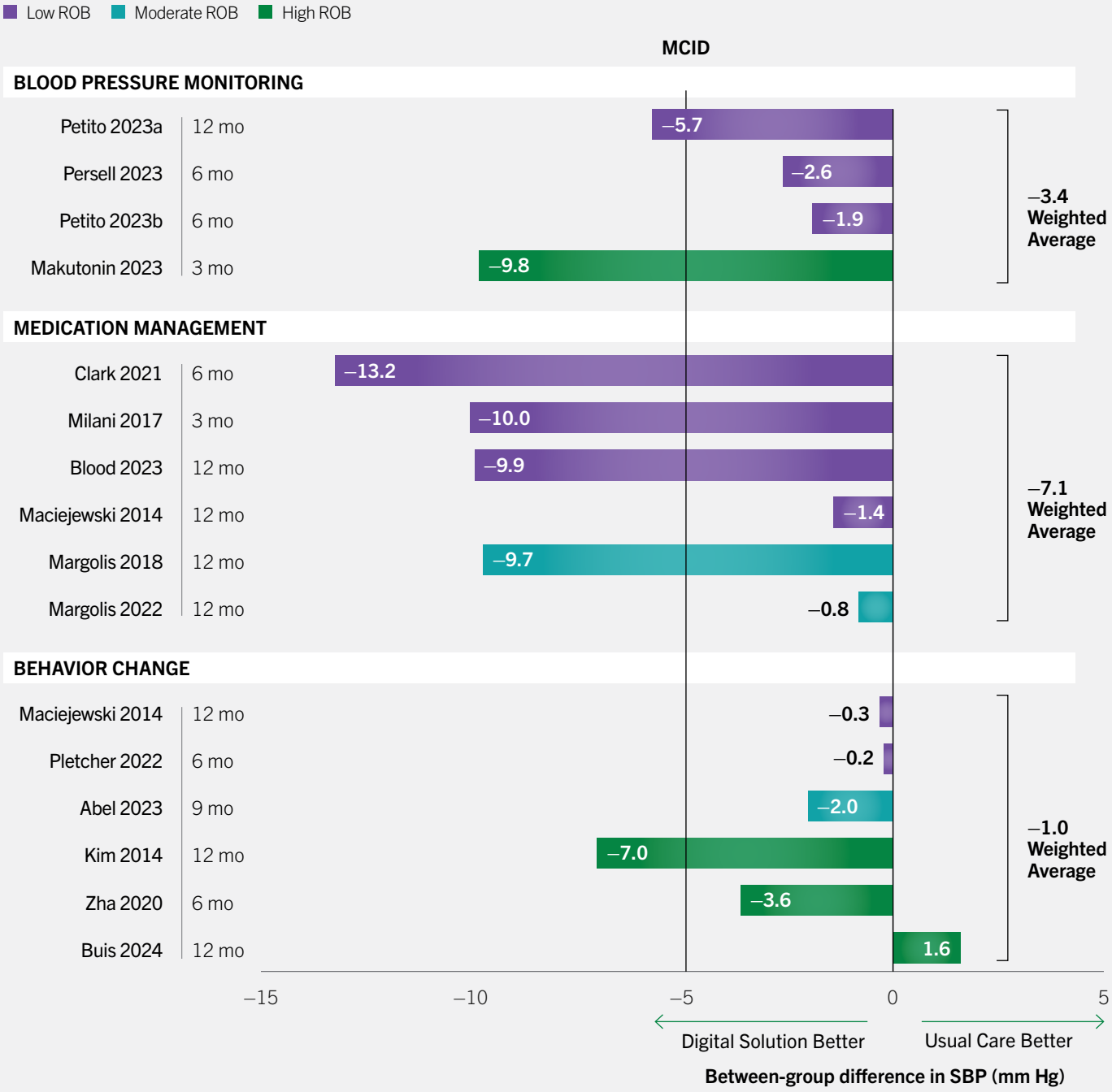
The three approaches — Blood Pressure Monitoring, Medication Management, and Behavior Change — had very different impact on hypertension improvements compared with usual care. To help with interpretation of study results for each approach, this assessment presents findings from individual studies, as well as weighted averages of results based on the number of digital solution users in the study sample (Exhibit 12). These averages are intended to facilitate rough comparisons between approaches.

Taken together, these findings demonstrate that the **Medication Management** approach has superior clinical outcomes, producing clinically meaningful and more rapid improvements in SBP compared with usual care. The other two approaches deliver marginal or modest benefits compared with usual care. Detailed findings by approach are described below, with full details in **Appendix D.**

* Three comparative studies were excluded from this portion of the analysis because they compared performance across digital approaches, rather than with usual care.

Exhibit 12

INCREMENTAL CHANGE IN SBP FOR DIGITAL SOLUTION APPROACHES COMPARED WITH USUAL CARE



Notes: MCID = minimum clinically important difference. Out of 15 studies with between-group differences, seven studies have data at 12 months. For the other studies, data from the longest follow-up timepoint was used: nine months (one study), six months (five studies), and three months (two studies). See Appendix D for individual study details. Maciejewski 2014 compares both Medication Management and Behavior Change approaches with usual care; this study is included in both approaches above. Weighted averages of between-group differences are shown to the right of the brackets. Averages are weighted by number of participants in the digital solution arm.

Blood Pressure Monitoring Approach

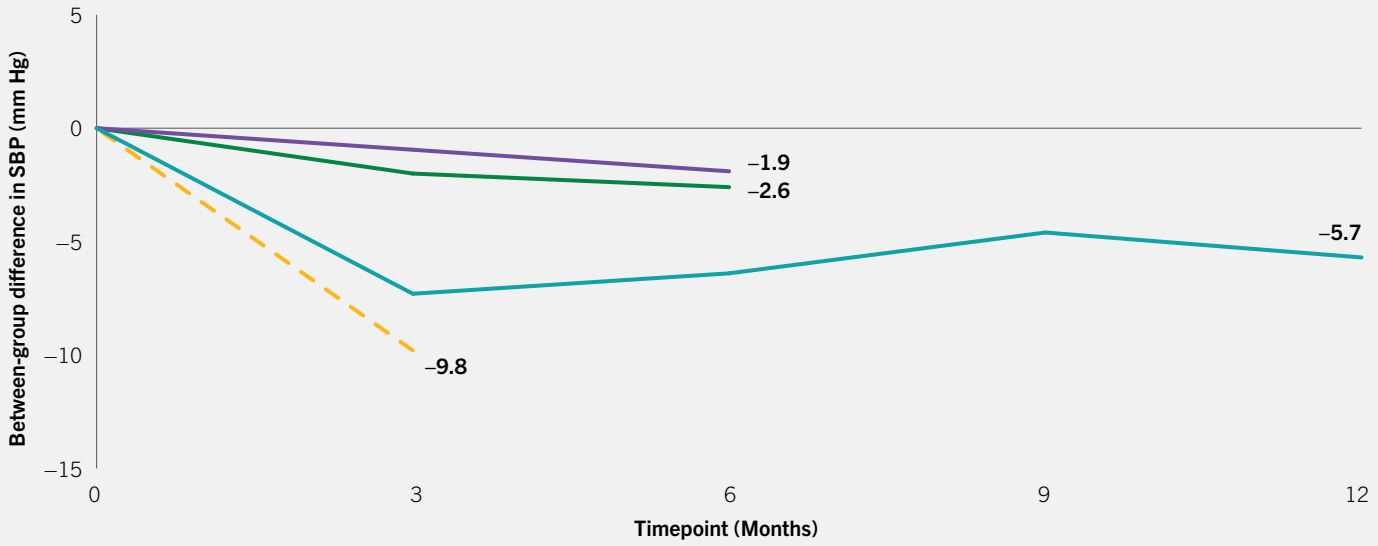
A **Blood Pressure Monitoring** approach to hypertension management showed slightly greater — but not clinically meaningful — declines in SBP compared with usual care and may help patients achieve SBP improvements faster (within three months) than usual care. However, most studies only reported results for six months or less, making the long-term benefits of this approach less certain. The results are also relatively variable, reflecting the heterogeneity of how provider practices respond to blood pressure monitoring data across studies and, likely, in the real world.

When compared with usual care, the **Blood Pressure Monitoring** approach improved SBP by an additional 3.4 mm Hg, on average. Study findings of the between-group difference ranged from 1.9 mm Hg improvement in SBP for the digital intervention to 9.8 mm Hg improvement (Exhibit 12). There were three studies with low risk of bias that used the VitalSight platform.[49–51] Only one of these studies found between-group SBP improvements that met MCID (5.7 mm Hg at 12 months).[52] There was one additional study with a high risk of bias that tracked a cohort of 100% Black patients with low socioeconomic status over a short duration.[53] It found that the blood pressure monitoring improved SPB by 9.8 mm Hg more than usual care at three months, but it did not include longer-term follow ups (Exhibit 13).

There were four SBP single-arm studies that report within-group changes from baseline with mixed risk of bias ratings. Qualitatively, these studies show results profiles similar to the digital intervention arms in the comparator studies. For instance, the single-arm SBP studies showed a weighted average improvement at six months of 7.6 mm Hg compared with 7.7 mm Hg in the comparative studies. Detailed results on each of these studies can be found in **Appendix F.**

Exhibit 13

DIFFERENCES IN SBP OVER TIME BETWEEN BLOOD PRESSURE MONITORING APPROACH AND USUAL CARE



Study (I/O)	Company	Risk of Bias	Sample Using Digital Solution[a]	Sample Includes Majority Underserved Population[b]
Persell 2023 (O)	VitalSight	Low	600	No
Petito 2023a (O)	VitalSight	Low	288	No
Petito 2023b (O)	VitalSight	Low	207	No
Makutonin 2023 (O)	Other	High	13	Yes

Notes: O = observational study. Solid lines indicate low or moderate risk of bias studies; dotted lines indicate high risk of bias studies. SBP at follow-up and between-group differences reported at final follow-up timepoint up to 12 months. Petito 2023a reported at 12 months. Persell 2023 and Petito 2023b reported at six months. Makutonin 2023 reported at three months. Negative between-group difference numbers indicate a larger SBP reduction in the DHT group vs. the usual care group. The four studies can be referenced in more detail in Appendix D under the Blood Pressure Monitoring Approach.

[a] Number of patients in the intervention arm of the study. [b] Majority of patients in the digital intervention arm represent diverse and historically underserved groups,including racial and ethnic minorities and low-income populations.

In the five comparator studies reporting on BPC, all showed more patients using **Blood Pressure Monitoring** achieved BPC compared with usual care, ranging from 3.6 to 17.2 percentage-point incremental BPC improvement over usual care at last follow-up (see **Appendix E** under the Blood Pressure Monitoring Approach). A good quality study with a nine month follow-up showed a 25-point increase in the proportion of patients achieving BPC in the digital intervention arm and only a 8-point increase in the usual care arm.[54] In another high-quality study reporting results at multiple timepoints, the proportion of patients achieving BPC was consistently at least 15 percentage points higher in the digital intervention arm than the usual care arm from three months through 12 months.[55] Detailed results on each of these studies can be found in **Appendix F.**

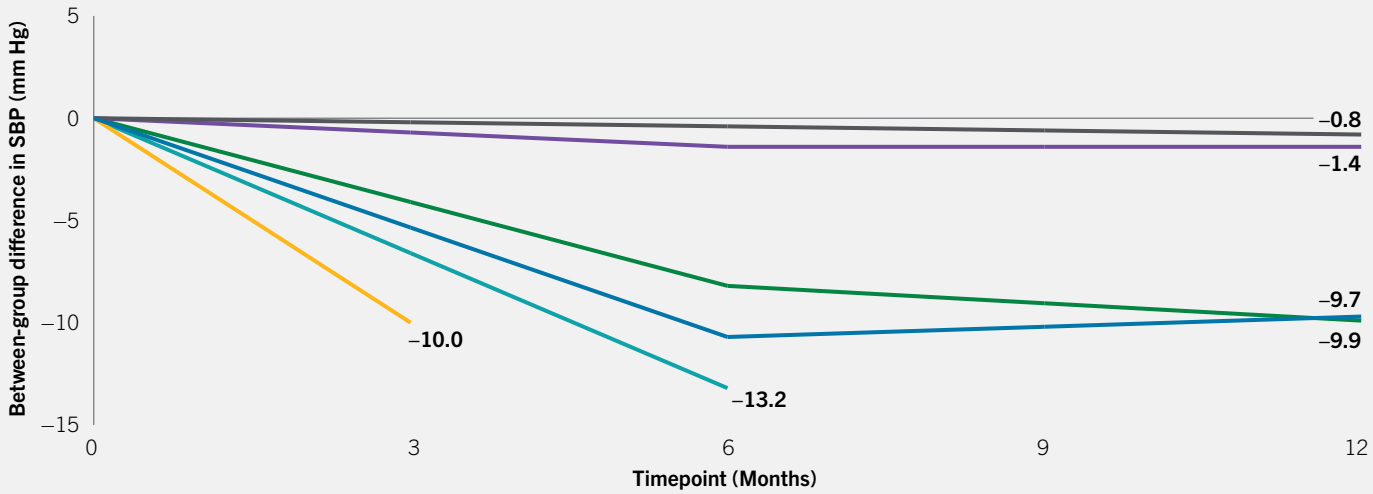
Altogether, the evidence suggests that improved **Blood Pressure Monitoring** can help providers track patients' progress on hypertension management and may accelerate and improve their ability to achieve reductions in SBP. However, because these solutions depend on the care teams to act on the monitoring data, overall performance of these solutions will vary by provider group.

Medication Management Approach

Evidence about the **Medication Management** approach shows that it can help patients achieve clinically meaningful and more rapid declines in SBP compared with usual care. The studies show large reductions in SBP as early as three months, with most reductions accruing by six months and sustained improvements through one year (Exhibit 14). Medication Management also helps more patients achieve BPC over time.

Exhibit 14

DIFFERENCES IN SBP OVER TIME BETWEEN MEDICATION MANAGEMENT APPROACH AND USUAL CARE



Study (I/O)	Company	Risk of Bias	Sample Using Digital Solution[a]	Sample Includes Majority Underserved Population[b]
Blood 2023 (O)	Other	Low	3,370	No
Clark 2021 (O)	Other	Low	118	Yes
Maciejewski 2014 (I)	Other	Low	149	No
Milani 2017 (O)	Ochsner Digital Health	Low	156	No
Margolis 2018 (I)	Other[c]	Moderate	228	No
Margolis 2022 (I)	Other[c]	Moderate	1,648	No

Notes: I = interventional study. O = observational study. All studies shown have low or moderate risk of bias. SBP between-group differences reported at final follow-up timepoint up to 12 months. Blood 2023, Margolis 2018, Margolis 2022, and Maciejewski 2014 reported at 12 months. Clark 2021 reported at six months. Milani 2017 reported at three months. Negative between-group difference numbers indicate a larger SBP reduction in the DHT group vs. the usual care group. The six studies can be referenced in more detail in Appendix D under the Medication Management Approach.

[a] Number of patients in the intervention arm of the study. [b] Majority of patients in the digital intervention arm represent diverse and historically underserved groups,including racial and ethnic minorities and low-income populations. [c] Studies use AMC technology to transmit blood pressure data. These are listed as "other" because the trials were designed to test the use of a non physician to control medication management. This study design is a function of the specific trial and is not testing/using an available feature of the AMC solution.

The **Medication Management** approach exceeded MCID, with an average between-group improvement in SBP of 7.1 mm Hg, ranging from 0.8 mm Hg to 12.3 mm Hg (Exhibit 12).Three well-designed observational studies showed meaningful improvements in SBP relative to usual care, ranging from 9.9 to 13.2 mm Hg (Exhibit 14).[56–58] One of these studies examined Ochsner Digital Medicine's solution and found a rapid 10 mm Hg improvement over usual care but only reported findings at three months.[59] A randomized controlled trial with moderate risk of bias also demonstrated clinically meaningful improvements (9.7 mm Hg at 12 months).[60] The speed of these improvements was also notable, with four studies achieving meaningful SBP improvements over usual care within six months. The number of well-designed studies and the consistency of their findings increase confidence that the medication management approach out-performs usual care for hypertension control.

Eleven single-arm studies of the **Medication Management** approach include data on within-group changes in SBP from baseline, most with a high risk of bias. These single-arm studies showed slightly better improvements in SBP at six months than what was found in the comparator studies (11.9 mm Hg in single-arm studies compared with 9.2 mm Hg in comparator studies). See **Appendixes F and G** for detailed results on each of these studies.

The three comparator studies that reported on BPC showed more patients using **Medication Management** achieving BPC compared with usual care, ranging from 8.9 to 40 percentage points higher BPC (see **Appendix E** under the Medication Management Approach). One low risk of bias study found that 71% of digital solution users achieved BPC within three months compared with only 31% of people in usual care.[61] Another good quality study with multiple timepoints based on veteran patients reported more modest differences (7.1 percentage-point improvement at six months and 8.8 percentage points more BPC at 12 months), but still showed better performance among patients using digital solutions versus those receiving usual care.[62]

Taken together, this is a robust body of evidence that consistently finds that **Medication Management** approaches outperform usual care. Because medication plays such an important role in hypertension treatment, interventions that assume full control over patients' medication regimens help speed up the pace of medication management to deliver superior SBP reductions compared with usual care. These solutions also help reduce the real-world variation in provider management of hypertension, including how quickly and effectively care teams adjust medications to achieve improved outcomes.

Behavior Change Approach

Evidence about the **Behavior Change** approach shows that it provides slightly greater — but not clinically meaningful — declines in SBP compared with usual care. Most of the evidence for the Behavior Change approach — in which patient self-management is the focus of the intervention — consists of studies with unique patient populations, including underserved patient groups representing racial and ethnic minorities, those with low socioeconomic status, or rural communities. This has two implications: (1) these findings provide insights into how digital solutions may perform in underserved communities, and (2) these findings may not be generalizable for a broader population. Unfortunately, none of the companies offering Behavior Change solutions in this assessment generated comparative evidence about SBP outcomes compared with usual care, making it difficult to draw direct conclusions about performance relative to usual care.

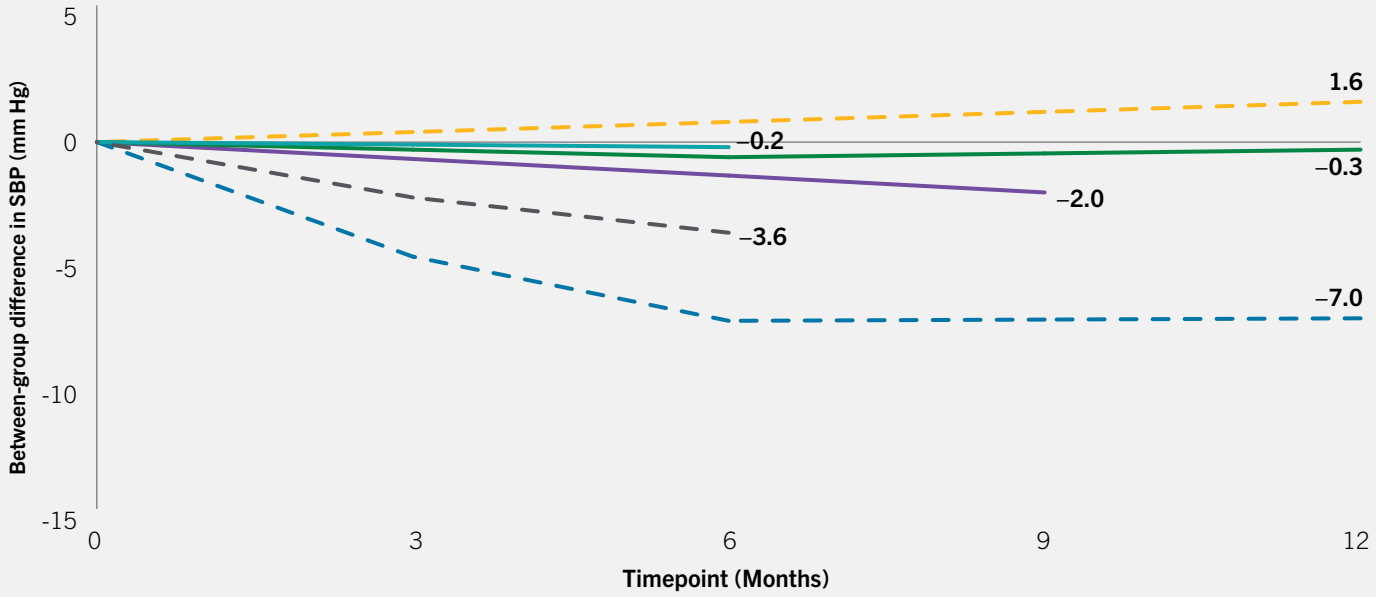
The comparative evidence on the **Behavior Change** approach suggests that digital solutions generate only small incremental SBP improvements (1.0 mm Hg) over usual care that do not meet MCID. The SBP results from six comparative studies ranged from 1.6 mm Hg worse than usual care to 7.0 mm Hg better than usual care (Exhibit 12).

The best quality evidence comes from two randomized controlled trials with low risk of bias, each of which found that **Behavior Change** approaches performed the same as usual care on SBP improvements. A study of patients with high starting SBP found a 0.2 mm Hg improvement in SBP over usual care.[63] Another study of veterans showed a 0.3 mm Hg SBP improvement over usual care[64] (Exhibit 15). Four randomized controlled trials with moderate to high risk of bias examined digital Behavior Change approaches in diverse or underserved communities, including a group of Korean American senior citizens,[65] a small sample of mostly (70%) obese Black women,[66] a 12-person study of mostly Black patients,[67] and a 83-person study of Black men and women.[68] Only one of these studies showed clinically meaningful improvements in SBP over usual care (7.0 mm Hg at six months).[69]

There were 15 SBP single-arm studies that reported within-group changes from baseline, including several abstracts that

Exhibit 15

DIFFERENCES IN SBP OVER TIME BETWEEN BEHAVIOR CHANGE APPROACH AND USUAL CARE



Study (I/O)	Company	Risk of Bias	Sample Using Digital Solution[a]	Sample Includes Majority Underserved Population[b]
Maciejewski 2014 (I)	Other	Low	148	No
Pletcher 2022 (I)	Other	Low	1,051	No
Abel 2023 (I)	Other	Moderate	45	Yes
Buis 2024 (I)	Other	High	83	Yes
Kim 2014 (I)	Other	High	184	Yes
Zha 2020 (I)	Other	High	12	Yes

Notes: I = interventional study. O = observational study. Solid lines indicate low or moderate risk of bias studies; dotted lines indicate high risk of bias studies. SBP between-group differences reported at final follow-up timepoint up to 12 months. Maciejewski 2014, Buis 2024, and Kim 2014 reported at 12 months. Abel 2023 reported up to nine months. Pletcher 2022 and Zha 2020 reported at six months. Negative between-group difference numbers indicate a larger SBP reduction in the DHT group vs. the usual care group. The six studies can be referenced in more detail in Appendix D under the Behavior Change Approach.

[a] Number of patients in the intervention arm of the study. [b] Majority of patients in the digital intervention arm represent diverse and historically underserved groups, including racial and ethnic minorities and low-income populations.

provided limited details on study methods and studies with a mixed risk of bias (see **Appendix F**). Most of these studies also focused on unique patient groups. The findings align with the findings from the comparator studies; the single-arm studies showed a weighted average improvement of 9.5 mm Hg in SBP at six months and the comparator studies showed 9.9 mm Hg improvement.

Two single-arm studies are worth highlighting because they both include a distinct group of patients with lower starting SBP than most of the other studies (134.2 and 130.7 mm Hg).[70, 71] Both studies effectively brought patients into or near the threshold for healthy blood pressure (118.9 and 122.9 mm Hg SBP), which is a notable marker of success. Further, they accomplished this in two underserved communities (rural and low-income), suggesting the behavior change approach may be helpful for patients who experience barriers to accessing usual care.

Among the three comparator studies that reported on BPC, all showed more patients using **Behavior Change** achieving BPC compared with usual care, ranging from 3 to 9.1 percentage points higher BPC (see **Appendix E** under the Behavior Change Approach). Evidence from two good quality studies suggests that the difference in improvements between **Behavior Change** and usual care are small across six and 12 months (3% and 3.8% differences at 6 months and 4% differences at 12 months).[72, 73] The one larger difference between groups (9.1%) was from a high risk of bias study.[74]

Secondary Outcomes

There are a number of secondary outcomes that help support patients' hypertension control. Several of these, including blood pressure measurement frequency and medication adherence, are indicators that patients are actively engaged in self-management and following their care plan. Others, like medication intensity, can be proxy measures for providers actively managing and adjusting patients' medication regimens. All studies reporting on secondary outcomes can be found in our **online data supplement.**

Blood Pressure Measurement Frequency

Evidence across multiple comparator and single-arm studies found that study participants generally followed clinical recommendations about when and how often to monitor their blood pressure. However, in a real-world setting, it is likely that patient adherence to recommended monitoring schedules may be diminished.

Most of the evidence suggests that blood pressure measurement activity alone is not associated with better SBP or BPC. However, there are two studies that were exceptions, both of which show that increased frequency of home blood pressure measurements was associated with lower SBP, even when controlling for patient demographic characteristics.[75, 76]

Medication Adherence

Studies reporting on medication adherence most often relied on self-reported measures from patients and results varied across the three approaches. The **Medication Management** approach showed some improvements in medication adherence over time. Multiple articles analyzing one moderate risk of bias randomized controlled trial examined medication adherence at different timepoints. At six months, digital solution users had a statistically significant improvement in self-reported medication adherence, whereas patients receiving usual care did not.[77] Another article that reported on adherence for the digital solution group found that the share of patients adhering to at least 80% of their medications — as evaluated by their pharmacist on the basis of patient self-report and review of pharmacy claims — increased from 49% to more than 90% by the end of the 12-month study.[78] However, another article found that a similar share of patients in both groups were adherent by 12 months — determined by the proportion of days covered by hypertension medications — and the difference between the two groups was not statistically significant.[79]

Findings for the **Behavior Change** approach were mixed. Three high risk of bias comparator studies generally found improvement in medication adherence over time for both digital solution users and those receiving usual care, but the between-group differences were not statistically significant.[80–82] Results from single-arm studies were also mixed and limited by sample size.

By contrast, the evidence we reviewed indicated that the **Blood Pressure Monitoring** approach did not show any improvement in medication adherence for digital solution users compared with those receiving usual care. Two studies reported on medication adherence: a randomized controlled trial found that self-reported medication adherence did not improve for digital solution users from baseline to six months and was similar to patients receiving usual care,[83] and a single-arm study found no significant change in patient adherence to medication or refills from baseline to three months.[84]

Medication Intensity

Studies reported on medication intensity, which is determined by the number of drug classes prescribed to the patient. Some studies report only on baseline medication intensity, while others report on changes therein (i.e., the number of medications that are added or removed from patients' medication list). All three approaches showed similar medication intensity patterns among digital hypertension solution groups and usual care groups. Generally, patients in both groups ended up with about the same number of medications by study end, which suggests that usual care and all digital approaches ultimately achieve similar outcomes for medication regimens, though the speed of adding medications may vary among them.

Patient Activation

Patient activation was measured in numerous ways across studies, including patients' engagement with their disease management and self-reported self-efficacy or confidence in managing one's disease, as well as education or knowledge of one's disease or management thereof. Across approaches, patient activation appeared to improve over time in both digital solutions and with usual care, with a few studies showing significantly greater improvement in the former.

Safety

Only four studies reported on adverse events.[85–88] In general, the adverse events profile across all intervention groups was

minimal but included a few reported events that varied in severity (e.g., symptomatic hypotension, angioedema).

User Experience

User experience — including measures of satisfaction and engagement — are important outcomes that impact patients' willingness to use digital solutions, the frequency and duration of their use, and ultimately, their clinical performance. Studies reporting on user experience can be found in our **online data supplement.**

Experience and Satisfaction

Across all approaches, patients reported positive user experiences throughout the duration of study involvement, suggesting good feasibility and acceptance of these digital solutions. Patients found that **Blood Pressure Monitoring** was useful and easy to use, self-monitoring was possible, and **Medication Management** approaches worked for them.

Few studies reported user experience findings from healthcare providers and staff who delivered or participated in the digital solutions. This is a significant limitation, since both the **Blood Pressure Monitoring** approach and the **Medication Management** approach are designed to integrate new data streams and patient management patterns into clinical workflows. Future research should include more in-depth assessments of how to optimally integrate these solutions into provider workflows to deliver clinical benefits without creating provider burden.

Engagement

Patient engagement measures are used to track the frequency of a patient's interaction with the digital hypertension management solution's program. Studies reported on user engagement with a variety of measures, including number of video visits, number of messages sent to the care team, number of conversations started on a discussion board, number of meals tracked, number of educational modules completed, and number of activities related to self-management. Across approaches and measures, the studies generally found strong patient engagement with digital solutions.

Health Equity

Hypertension prevalence and severity vary by age, race and ethnicity, socio-economic status, and geography. The majority of studies in this analysis reported detailed demographic information about their study participants, which is important to understand how solutions perform across diverse patient populations **(see online data supplement).** Furthermore, many of the studies of digital hypertension solutions were specifically designed to test outcomes in specific patient groups and sub-populations, including numerous studies enrolling a disproportionate sample of diverse racial and ethnic groups, low-income communities, and veterans.

Broadly speaking, the evidence tells a positive story about the potential role of digital hypertension management solutions in both serving diverse patient populations and helping to close care gaps among underserved communities. Digital hypertension management solutions were found to be effective across demographic groups, including age, gender, and rural and urban settings. Two studies assessing **Medication Management** and **Behavior Change** approaches specifically tested whether the benefits they found in SBP and BPC differed across patient characteristics. They found the solutions perform comparably well across race, gender, age, and preferred language.[89,90] Notably though, several studies that were exclusively focused on specific, non-white racial and ethnic groups showed greater benefits to hypertension control than the rest of the literature.

Taken together, these studies show that people who cannot access or are not able to engage in care do benefit from hypertension management when it is provided in a way that works for them. If the care they do engage or access is via digital hypertension management solutions or a viable usual care pathway, they can work. That said, digital hypertension management solutions alone are not a substitute for engagement with a primary care provider.

Race and Ethnicity

Eleven studies (>18%) included patient samples consisting entirely of specific racial and ethnic groups. Four studies showed clinically meaningful change from baseline SBP among patients from Black, Hispanic, and Asian American populations.[91–94] However, two comparative studies in Black patients showed clinically meaningful decreases in SBP, but no benefit relative to usual care.[95,96] The result profile for BPC was similar.[97–103]

Age and Gender

Six studies reporting on primary health outcomes in patients over 60 years of age found similar improvements in SBP and BPC across older and younger users of digital solutions.[104–113] In a study of patients over 65 years old, the **Medication Management** approach performed significantly better than usual care plus education after three months (13.9 mm Hg vs. 4 mm Hg decrease, respectively).[114] Four studies presented primary outcomes

by gender. In all cases, findings on SBP and BPC demonstrated comparable benefits among male and female patients.[115–119]

Geographic Location

Only seven studies reported on geographic location of study participants.[120–126] Across these studies, findings on SBP and BPC generally showed that digital hypertension management solutions are effective in both rural and urban communities.

Clinical Effectiveness Ratings by Approach

Based on PHTI's review of clinical evidence, digital hypertension management solutions improve hypertension control as well as or better than usual care. The solutions have been examined widely across diverse patient populations and are shown to be effective across age, gender, race, ethnicity, and geography of the users. The evidence suggests that focused hypertension management in general, including using digital solutions, is particularly effective in underserved populations who might not otherwise have good access to high-quality care. Secondary outcomes and user experience measures were generally positive across the literature.

- **Blood Pressure Monitoring** approaches reduce SBP slightly greater compared to usual care, but improvements are not clinically meaningful and vary depending on how the care team acts on the data.
- **Medication Management** approaches produce more rapid declines in SBP compared with usual care, which produce clinically meaningful health benefits.
- **Behavior Change** approaches provides limited incremental declines in SBP compared with usual care but may help underserved populations achieve their care goals.

Across the three approaches to digital hypertension management, the evidence indicated that the **Medication Management** approach has the most substantive evidence of superior performance, showing patients achieve rapid improvements in SBP that exceed MCID compared with usual care. These solutions also produce larger improvements in the proportion of patients achieving BPC compared with usual care. By outsourcing medication management to dedicated, virtual care teams, these solutions accelerate SBP reductions compared with what most providers can achieve with in-person visits. Based on the ICER Evidence Rating Matrix, these Medication Management solutions have an "Incremental or Better" (B+ rating) comparative net health benefit, given their substantial net benefit and high certainty in the evidence.

The **Blood Pressure Monitoring** approach has a smaller evidence base to support improvements in clinical outcomes — at levels that did not meet MCID for SBP — compared with usual care. By delivering regular home monitoring of blood pressure, often accompanied by clinician notifications and recommendations, these solutions give regular SBP feedback to providers that enables medication management and other adjustments to the care plan. However, data that is not acted on does not contribute to better patient outcomes. Based on the ICER Evidence Rating Matrix, these Blood Pressure Monitoring solutions have a "Comparable or Better" (C++ rating) comparative net health benefit, given their moderate evidence certainty and their small net health benefit.

The evidence indicates that the **Behavior Change** approach does not meet MCID for SBP compared with usual care, but evidence shows this approach to deliver notable clinical improvements in underserved populations. By supporting patient hypertension self-management and education, these solutions may help close access and equity gaps in traditional care models. Based on the ICER Evidence Rating Matrix, these Behavior Change solutions have a "Comparable or Incremental" (C+ rating), given their moderate-to-low evidence certainty and comparable net benefit to usual care.

While the body of evidence for digital hypertension management solutions is generally robust, additional evidence generation in this space should prioritize studies with longer-term follow up to show the durability of effects past one year. Combined approaches that bring together monitoring, medication management, and behavior change may have potential for substantial and lasting clinical benefits across a wide range of patients and warrants further study.

Exhibit 16

INCLUDED COMPANIES BY APPROACH

Blood Pressure Monitoring	Medication Management	Behavior Change
AMC Health	Cadence	Dario
HRS	Ochsner Digital Medicine	Hello Heart
VitalSight	Story Health	Lark
		Omada
		Teladoc (Livongo)

Solution-Specific Analysis

This section provides an overview and summarizes the clinical information on 11 digital hypertension management solutions included in the report. Although the solutions can be broadly categorized into three approaches on the basis of how they drive blood pressure change, each solution includes unique features, user engagement approaches, staffing models, and pricing (see Exhibits 16 and 17).

Eight of 11 companies in this report chose to engage with PHTI during the assessment process, and six companies submitted evidence for review. Confidential business information was used to inform the assessment but is not represented in the final report. Throughout the process, PHTI held meetings with companies to better understand their solutions. PHTI provided companies the opportunity to review company-related information in the report prior to publication. Clinical summaries are based on the full literature review, including company-submitted evidence.

Eight of the companies have published clinical evidence about their digital solution. Three companies including Dario, HRS, and Story Health had no evidence that met the inclusion criteria for this review. VitalSight has the most robust body of evidence, with three low risk of bias comparative studies against usual care. In addition, Ochsner Digital Medicine has one well-designed comparative study (see Exhibit 18). In the Behavior Change approach, only Lark produced a comparator trial, and none of the companies produced company-specific comparative evidence against usual care. This evidentiary gap makes it difficult to understand the clinical impact of these solutions beyond the consistent improvements observed across all studies with well-managed usual care. Given the consistency in the mechanism of action within approaches to digital hypertension management, it is likely that findings for one company using a particular approach will apply to solutions that use a similar approach. However, variation in solution design, user interface, and the care model using the solution may produce measurable differences in outcomes. All companies should continue to generate evidence of clinical performance to confirm their solutions align with the outcomes of the approach as a whole.

Blood Pressure Monitoring Approaches

Based on the clinical effectiveness of **Blood Pressure Monitoring,** company studies and solutions that provide slightly greater, but not clinically meaningful (less than 5 mm Hg) declines in SBP compared with usual care are in line with this approach.

AMC Health offers a remote monitoring solution that provides patient data to physicians and care teams for a range of chronic conditions. For hypertension, the platform uses a connected blood pressure cuff to upload patient home-monitoring data directly to provider EHR systems. The solution uses analytic tools to help clinical teams monitor and identify patients who need additional focus. Some configurations include human coaches/clinical staff who monitor the data and

Exhibit 17

CORE COMPONENTS OF DIGITAL HYPERTENSION MANAGEMENT SOLUTIONS

● ● ● Standard Feature ○ ○ ○ Available Feature

	BLOOD PRESSURE MONITORING APPROACH			MEDICATION MANAGEMENT APPROACH			BEHAVIOR CHANGE APPROACH				
CATEGORY Features	AMC Health	HRS	VitalSight	Cadence	Ochsner Digital Medicine[a]	Story Health	Dario	Hello Heart	Lark	Omada[b]	Teladoc (Livongo)[c]
PERSONNEL											
Has a clinician (prescribing) that provides virtual visits and can prescribe medication		●		●	●	●			○		○
Has an AI-based coach focused on behavior and lifestyle management, patient education, and/or medication adherence education								●	●		
Has a human coach/care team (non-prescribing) focused on behavior and lifestyle management, patient education, and/or medication adherence education	●			●	●	●	●		●	●	●
DATA COLLECTION											
Blood pressure	●	●	●	●	●	●	●	●	●	●	●
Automated medication tracking/adherence tracking (e.g., tracking refill data)					○	●					●
Patient-reported medication adherence		●		●	●	●	●	●	●	○	●
DATA SHARING											
Automated data sharing with patient's primary doctor through EHR integration	●	●	●	●	●	●					○
Data sharing with patient's primary doctor is optional/available		●		●	○	●		●	○	●	●

Source: Public information (websites, marketing materials, company-provided public information, etc.).

Notes: [a] Refill data, as available, is reviewed as needed based on patient intervention; data sharing with patient primary doctor is optional/available for patients without a direct integration. [b] Assesses medication adherence through a periodic survey. [c] Automated data sharing with patients' primary doctor is available through EHR integration if a Teladoc clinician is the patients' primary care provider.

support the provider, as well as a library of patient-facing educational content. The company offers performance guarantees for some solution offerings.

AMC Health's solution does not include prescribers who are employed by the digital solution. However, the clinical studies that use the AMC Health solution were designed so that blood pressure monitoring data were delivered directly to a pharmacist who had a high degree of control over medication titration.[127, 128] This particular pathway was dependent on specifics of the study design and is not a feature that is included as part of the AMC product.

As such, while these studies were conducted with the AMC Health platform, they are not representative of the expected non-trial performance of the AMC Health solution. Evidence from these studies is discussed under the **Medication Management** approach in the clinical effectiveness section.

Exhibit 18

RISK OF BIAS OF CLINICAL STUDIES, BY COMPANY IN EACH APPROACH

Notes: ROB = risk of bias. N/A = not applicable. Comparative studies are defined as those that include a DHT and usual care arm. Noncomparative studies are defined as those that do not compare DHT and usual care arms. [a] AMC Health's product is categorized in the Blood Pressure Monitoring approach, but studies identified in the systematic literature review that use this solution examine the Medication Management approach and are categorized as such in the clinical effectiveness section.

Two additional AMC Health–supplied studies were excluded because they were conducted prior to the review timeframe (2014–2024).[129, 130] One study was a cluster-randomized clinical trial that compared usual care with an intervention of home blood pressure telemonitoring and pharmacist case management.[131] This study involved pharmacist medication management and was supportive of the findings for the **Medication Management** approach. The other study was focused on type 2 diabetes instead of hypertension.[132]

HRS offers an RPM and telehealth platform that extends care for primary hypertension providers and post-hospitalization care. Patients receive a connected blood pressure cuff that can populate data into the provider's existing EHR. The system sends patient-focused digital education content and automated interactive voice calls to encourage adherence to medication and care plans. Providers can monitor risk alerts and communicate with patients in real time through video, phone, and SMS.

HRS did not submit data, and the systematic literature review did not identify any relevant clinical studies. However, given that the HRS mechanism of action is similar to others in the Blood Pressure Monitoring approach, this report concludes that it is likely to perform in line with other solutions that take a similar approach.

VitalSight is an RPM platform for providers sold by medical device maker Omron. Patients receive a connected blood pressure cuff and scale to take measurements at home. The readings populate in the provider's EHR or in a physician-facing dashboard for tracking and analysis. Blood pressure readings above given thresholds trigger alerts for the treating clinician to consider care plan or medication adjustments.

The seven articles from three comparative trials for VitalSight met inclusion criteria and constitute the majority of the data on the Blood Pressure Monitoring approach.[133–139] All studies had a low risk of bias and compared the VitalSight solution with usual care over 3–18 months. These studies demonstrated a small net benefit in the reduction of SBP relative to usual care, with only one study reporting a clinically meaningful between-group difference of 5.7 mm Hg favoring the digital intervention arm at 12 months.[140] VitalSight's studies generally demonstrated a faster and steeper SBP decline in the digital intervention arm, with the usual care arm showing a slower decline of a smaller magnitude.[141–144]

Medication Management Approaches

Based upon the clinical effectiveness of **Medication Management,** company studies and solutions that exceed MCID (>5 mm Hg reduction in SBP compared with usual care) are in line with this approach. A common feature of these approaches is the inclusion of a licensed prescriber — often a clinical pharmacist — in the solution.

Cadence offers a solution for hospitals and clinics seeking to outsource intensive medication management, monitoring, and education services to their patients with hypertension, heart failure, and type 2 diabetes. The system provides patients with a connected blood pressure cuff and other monitoring devices. Data from those devices are monitored by a remote multidisciplinary team employed by Cadence under the supervision of the ordering provider. The Cadence team consists of doctors, nurses, and nurse practitioners who are licensed in the states where they practice, under supervision of Cadence's medical directors. Cadence clinicians can manage patient medications and order labs on the basis of patient data, in collaboration with the ordering provider via clinical care protocols, all of which can be sent to populate in the provider's existing EHR. Clinical staff also personalize lifestyle and behavior recommendations and provide medication adherence education during virtual visits, as needed. Cadence offers performance guarantees.

Cadence had one abstract summarizing results of a noncomparative clinical study included in the evaluation.[145] This single-arm study of 4,006 patients found SBP decreased by 9 mm Hg over 4–5 months of follow up. While this was a single-arm observational study, the findings are in line with overall performance of interventional groups in the Medication Management approach.

Ochsner Digital Medicine is a digital hypertension management solution that is owned by Louisiana-based integrated health system Ochsner Health. Ochsner Digital Medicine provides patients with a connected blood pressure cuff to take readings that are automatically shared with a care team consisting of pharmacists, physician assistants, physicians, health coaches, and dietitians. The team uses patient data, clinical data (as available), and information gathered via interactions to provide personalized health coaching and medication management. All patient data are recorded in the EHR and are available to the patient's primary doctor. Ochsner Digital Medicine offers performance guarantees based on the size of the population and may include metrics around nonclinical and clinical components.

Ochsner Digital Medicine produced the most robust evidence for the **Medication Management** approach with three studies.[146–148] Studies included one low risk of bias comparative study[149] and two noncomparative studies with a high risk of bias.[150, 151] The comparative observational study showed a decline in SBP for the digital intervention group (14 mm Hg) versus usual care (4 mm Hg) (statistical significance was not reported).[152] A second study demonstrated mean statistically significant reductions in blood pressure variability† (a reduction of 23%) after 24-months participation in the digital program.[153] A third study examined the clinical effectiveness of the digital intervention by race (i.e., Black and white) and a number of health barriers (i.e., financial strain, health literacy, and patient activation).[154] It found that among both Black and white patients, those with zero health barriers were significantly more likely than patients with one or more health barriers to achieve BPC. Overall, these finding were in line with other studies in the Medication Management approach.

Nine company-submitted evidence and data sources were excluded from the analysis.[155–163] Of these, seven were review articles primarily focused on discussions of innovative approaches to hypertension management.[164–170] One submission was a podcast,[171] and one was an abstract that was beyond the conference search timeframe.[172]

Story Health is a digital health solution that uses digital tools and virtual providers to enable virtual oversight and management of patients with hypertension. Story Health is designed to triage and manage hypertensive patients and reduce the need for PCPs or cardiologists to provide day-to-day management. Story Health offers a digital clinical care team consisting of cardiologists, cardiac nurse practitioners, registered nurses, and health coaches who review patient data from connected devices and can provide medication management services. Patient data is integrated into the provider's EHR. Story Health offers performance guarantees.

Story Health did not submit any data, nor did the systematic literature review identify any relevant clinical studies. Given that the Story Health mechanism of action is similar to others in the **Medication Management** approach, this report concludes that it is likely to perform in line with the other companies that take a similar approach. That said, Story Health should produce evidence of its performance to more clearly demonstrate the clinical outcomes it can deliver.

Behavior Change Approaches

Based on the clinical effectiveness of **Behavior Change,** company studies and solutions that showed limited incremental declines in SBP are in line with this approach.

Dario's cardiometabolic solution is a behavior change program that manages hypertension as part of an overall platform that includes diabetes and weight management. Dario's solution provides at-home management tools, 1:1 coaching, and algorithmic data analysis and content. Dario provides a connected blood pressure cuff for tracking and communicates progress updates and personalized content directly to patients. Patients also have access to live sessions with "clinical coaches," including certified educators, registered nurses, and pharmacists.

Dario did not submit any data, nor did the systematic literature review identify any relevant studies. Dario's website includes a focus on hypertension with reported outcomes, but PHTI could not verify the sources or references for the claims.[173–175]

Hello Heart offers a fully automated self-management and lifestyle coaching solution that addresses hypertension as part of a cardiovascular risk-reduction program. The system analyzes patient data from a connected blood pressure cuff, along with other user-input data, to provide personalized feedback, medication reminders, and lifestyle coaching. The system works without input from a treating physician but allows patients to share health data with their doctors and input physician-prescribed medication regimens. Hello Heart offers performance guarantees on the basis of clinical and economic metrics.

Data from Hello Heart included three studies from the literature review and one company-submitted study.[176–179] All four were single-arm observational studies and the three studies that could be assessed for risk of bias all were scored as high risk.[180–182]

One study, a pre-post observational study with a large population (n = 41,794) examined the durability of SBP improvements for Hello Heart users.[183] It found that the mean reduction in SBP at 12 weeks was 9.56 mm Hg in patients with baseline SBP between 130–139 mm Hg and reductions were stable over 2 years (10.1 mm Hg). Patients with higher

† SBP variability was determined on the basis of the standard deviation of all recorded SBPs by patient each month, and was divided into quartiles (<10.3, 10.3–12.7, 12.7–15.6, ≥15.6 mm Hg).

baseline SBPs (≥140) achieved a larger mean reduction during these timepoints (15.6 and 18.6 mm Hg, respectively). However, an important limitation of this study is that it only reported outcomes for patients that had SBP reductions.

Another large study (n = 28,189) examined SBP improvement and the durability of effects and found those that engaged with the solution for up to three years were able to maintain SBP reductions.[184] Average SBP eductions were 12.2 and 20.9 mm Hg for patients with stage 1 and stage 2 hypertension, respectively.

Data from a conference poster evaluated the impact of the digital program across subgroups and found a significantly better SBP improvement in women compared to men, whereas SBP changes were similar across age, race, and preferred language. Average SBP reductions were 9.87 and 16.7 mm Hg for patients with stage 1, and stage 2 hypertension, respectively.[185] Finally, one study examined the impact of engagement intensity and found that patients in the medium or hig engagement groups were significantly more likely to achieve blood pressure reduction than those in the low engagement group — a likelihood of 22% versus 10%.[186]

Broadly, the reductions in SBP are difficult to qualify due to these studies not including comparator arms; however, the evidence suggests that hypertension improvements for Hello Heart are in line with the performance of the **Behavior Change** approach overall.

Lark is an automated solution for patients who want to self-manage their hypertension at home. The program offers personalized behavioral and health coaching and patient feedback, including interactions with a conversational AI coach on the patient's smartphone. Patients obtain a connected blood pressure cuff to collect data for automatic or manual entry into the Lark platform. The system alerts Lark health coaches and instructs patients to call their doctor if extremely high readings are detected, and it delivers nudges and calls to action to engage with the platform.

Three observational studies from Lark met the inclusion criteria.[187–189] One study with a low risk of bias examined the impact of the Lark program on patients in three baseline SBP range categories (120–129, 130–139, and ≥140 mm Hg).[190] At three and six months, those with baseline values of ≥130 mm Hg demonstrated clinically significant reductions in SBP (–7.3 mm Hg for stage 1 and –13.0 mm Hg for stage 2 at six months). Another study of 297 adults (35% of whom were Black), with a moderate risk of bias, found no difference in SBP reduction between participants randomized to a smartphone coaching app or to a blood pressure tracking app with no coaching[191] A third study, with a moderate risk of bias, examined the impact of age on engagement and found patients aged 65 and older had significantly higher levels of engagement than younger adults.[192]

Overall, this report concludes that these findings are in line with the **Behavior Change** approach's performance. The evidence for Lark suggests that it performs in line with the overall approach findings of limited incremental declines in SBP compared with usual care.

Omada's program for hypertension is a lifestyle change solution for the self-management of hypertension between doctor visits. The approach combines analysis of data from a company-provided connected blood pressure cuff with human-led behavior coaching and online educational programming. Patients are paired with an Omada care team that includes a health coach and a hypertension education specialist who communicates via asynchronous messaging. The solution includes peer-group support and "check-ins" in which patients are advised to ask healthcare providers about medication adjustments. The program follows a care plan created by the patient's regular doctor. Omada offers performance guarantees for some clients that are based on clinical performance for a subset of the population.

Two single-arm studies from Omada met the inclusion criteria.[193, 194] Both had a high risk of bias. One short-term study found a 14% increase in medication adherence and a reduction of 7 mm Hg in SBP over three months.[195] The study also examined the impact of the Omada program on patients at different hypertension stages and found statistically significant improvements of 10.3 mm Hg for patients who started the program with stage 2 hypertension. The other article examined the impact of the Omada program over 12 months and found a decrease of 8.1 mm Hg in those with starting SBP of >130 mm Hg (in those with starting SBP of <130 mm Hg, there was a small increase in SBP at 12 months).[196]

One company-submitted article did not meet inclusion criteria because the population was out of scope.[197] Overall the evidence reviewed suggests that Omada's results are in line with the findings for the **Behavior Change** approach.

Teladoc's (also known as Livongo) program for hypertension, is a digital solution designed to support patients living with hypertension and other chronic conditions. The program provides a connected blood pressure cuff that uploads readings for digital monitoring. Teladoc (Livongo) delivers automated educational content on healthy habits related to hypertension and offers scheduled 1:1 access to resources, such as certified health coaches and registered dietitians for goal setting and lifestyle education. The system sends patients personalized reminders, offers weekly summaries and recommendations, and provides tracking reports that patients can share with their doctors. Under certain conditions, high-acuity patients can be connected with a licensed Teladoc clinician who may prescribe and adjust medications when clinically appropriate. Teladoc puts their full program fees at risk and offers performance guarantees based on specific target outcomes.

Three Teladoc studies met the inclusion criteria.[198–200] One study had moderate risk of bias,[201] one had a high risk of bias,[202] and one could not be rated as it was an abstract of a conference poster.[203] The abstract (and conference poster) examined medication adherence and found marginal increases for those enrolled in the program.[204] One single-arm study examined the impact of enrollment in multiple digital health behavior change programs simultaneously and found concurrent program enrollment was associated with greater SBP reductions.[205] Last, a study examining the impact of COVID-19 on hypertension found the proportion of Teladoc enrolled patients classified as uncontrolled or severely uncontrolled hypertensives was 11% higher during the pandemic than before.[206]

Five submitted articles did not meet inclusion criteria.[207–211] Three were excluded because they did not focus on BPC.[212–214] Two conference abstracts were outside of the search timeframe.[215, 216] One abstract reported a moderate but not clinically meaningful improvement in SBP of 3.0 mm Hg at 12 weeks, with those who had starting blood pressure greater than 140/90 mm Hg reporting larger decreases over 12 weeks.[217] The other abstract is a propensity score matching and a difference-in-difference analysis that estimated gross medical savings of $81 per member per month and is described in the economic section of this report.[218]

This report concludes that these studies support the findings that the **Behavior Change** provides limited incremental declines in SBP compared to usual care.

Economic Impact

Purchasers provide digital hypertension management solutions to drive more reliable health improvements than usual care alone. However, the solutions can have wide variation in pricing, and healthcare resources are finite. Therefore, purchasers closely scrutinize the budget impacts of digital solutions for hypertension care relative to the health improvements, and corresponding care savings, they generate. When evaluating the budget impact of a digital solution, up-front spending on services and medication and long-term trends in healthcare utilization at the population level are reviewed.

Hypertension that remains uncontrolled is associated with higher overall healthcare spending and more physician visits than when blood pressure is controlled.[219] Studies show the effect is progressive: Higher average systolic blood pressures are significantly correlated with increasing levels of healthcare spending on medications and physician visits.

Accordingly, purchasers may experience lower overall spending if patients lower their blood pressure and achieve stable control that results in reductions in both outpatient services and risks for hospitalization from cardiovascular disease and mortality.

The Economic Burden of Hypertension

Hypertension is a common chronic condition associated with significant increases in healthcare spending relative to non hypertensive individuals. One widely cited 2018 study estimated that the adjusted annual incremental healthcare spending for adults is $131 billion higher for those with hypertension than for those who do not have high blood pressure.[220] On a per-person basis, adjusted healthcare spending is $1,920 per member per year (or $160 per member per month) higher for those with hypertension than for peers without it. The largest components of that cost, in descending order, are inpatient care, outpatient care, and medication.

Uncontrolled hypertension is a major risk factor for developing heart disease and stroke — leading causes of mortality[221] and healthcare spending.[222] Lowering blood pressure is associated with significant reductions in the relative risks of heart disease and stroke. A large meta-analysis of clinical trials for blood pressure–lowering medications found that reductions of 10 mm Hg of systolic pressure or 5 mm Hg of diastolic pressure were associated with a 22% risk reduction for coronary heart disease and a 41% risk reduction for stroke.[223]

The costs associated with patients who have uncontrolled hypertension are notably higher than those for patients with controlled hypertension. One analysis found that patients whose blood pressure is maintained at the threshold between stage 1 and stage 2 hypertension incur average annual medication costs of $326 per person, compared with $431 among those with pressure greater than 140/90 mm Hg and $578 among those with pressure above 160/100 mm Hg.[224] The same analysis found that patients with diastolic pressures indicating stage 2 hypertension averaged 4.5 more physician office visits over a two-year period than those in stage 1.

Assessing the economic impact of digital hypertension management solutions requires careful examination of the incremental health benefits and cost savings from increased technology spending versus the costs of usual care. If spending on digital solutions leads to higher rates of BPC and lower costs of medication, office visits, and hospitalizations over the long term that exceed the cost of the digital solution, they will deliver both clinical and economic benefits. However, many programs increase medication and outpatient care utilization while decreasing hospitalizations, and these programs may improve clinical care but may not have net positive economic benefits.

Budget Impact Model Methodology

The budget impact model seeks to estimate the expected one- and three-year changes in total healthcare spending that result from offering digital hypertension management solutions across a hypothetical one million-member plan. The model estimates the number of people who could be eligible for digital hypertension management solutions, the gross reduction in expected healthcare spending resulting from improved BPC for patients enrolled in these programs, and the net impact on health system spending once such

savings are offset by spending on the digital hypertension management solutions.

Based on the clinical effectiveness results above, the budget model estimates the impact of digital hypertension solutions on healthcare spending in three scenarios to reflect the three approaches to digital hypertension management: 1) **Blood Pressure Monitoring** solutions, 2) **Medication Management** solutions, and 3) **Behavior Change** solutions.

There are three primary components of the budget impact:

1. **Eligible population** — The total number of patients who may qualify for a digital hypertension management solution, if broadly implemented;
2. **Reduced costs from health improvements** — The changes in healthcare spending that result from improved blood pressure under usual care and digital hypertension solutions; and
3. **Technology price** — The price paid to a digital health technology company (under a contractual agreement) or to a provider (under RPM reimbursement).

These components come together to estimate the net impact on healthcare spending per user of a digital hypertension management solution and the overall per member per month impact of that spending across all enrollees in a hypothetical one million-member plan.

Eligible Population

The model estimates the number of adults with hypertension who regularly monitor their blood pressure across commercial insurance, Medicare, and Medicaid. In the United States, an estimated 45.1%, 74.1%, and 47.3% of adults have diagnosed hypertension in commercial, Medicare, and Medicaid plans, respectively.[225] Among people diagnosed with hypertension, 51.2% of patients surveyed reported regularly monitoring blood pressure.[226] Therefore, approximately 18.2% of all commercial enrollees, 37.6% of Medicare beneficiaries, and 11.8% of Medicaid beneficiaries are eligible to receive digital hypertension management solutions. When estimating the budget impact of these solutions, the model assumes a 25% participation rate in digital hypertension management solutions among all eligible individuals (see Exhibit 19).

Reduced Costs from Health Improvements

The budget impact model calculates the reduced risk of cardiovascular disease events and decreased costs on the basis of improvements in SBP between

Exhibit 19

ESTIMATING THE ELIGIBLE POPULATION FOR DIGITAL HYPERTENSION MANAGEMENT SOLUTIONS

	Commercial	Medicare	Medicaid
PROPORTION OF ENROLLEES WHO ARE ADULTS	78.9%	99.2%	48.7%
PREVALENCE OF DIAGNOSED HYPERTENSION	45.1%	74.1%	47.3%
PATIENTS WHO REGULARLY MONITOR BLOOD PRESSURE	51.2%	51.2%	51.2%
TOTAL ELIGIBLE POPULATION FOR DIGITAL HYPERTENSION MANAGEMENT SOLUTIONS	**18.2%**	**37.6%**	**11.8%**

individuals receiving usual care and those enrolled in a digital hypertension program, as reported in the clinical literature.

To estimate the impact of reducing blood pressure on cardiovascular disease risk, the model applies the ACC's and AHA's Pooled Cohorts Equations (PCE), which estimate the 10-year risk of developing atherosclerotic cardiovascular disease risk.[227] The budget model includes heart attack, stroke, and heart failure as events in the analysis, as these are the most commonly reported and costly events. The model also annualizes the PCE risks, assuming even distribution of cardiac events across 10 years. This assumption is likely to overestimate healthcare savings in the three-year model, given that a disproportionate share of the savings may be in the later years. The PCE uses age, gender, race, total and high-density lipoprotein cholesterol levels, treated SBP, and whether patients are diabetic or smokers as variables to calculate cardiovascular disease risk. This analysis assumes that all patient characteristics other than the impact on SBP remain equal between the digital solution and usual care arms.[228, 229]

Weighted average changes in SBP between the digital solutions and usual care for each approach are taken from all comparative clinical studies identified in the literature review and described above in the primary clinical outcomes section for each approach (see **Appendix A** for a detailed methodology). The model assumes that patients maintain the SBP improvements over the three-year budget window. Cardiovascular disease event costs are estimated on the basis of per-patient spending and probabilities of fatal and nonfatal events from published literature.[230–234]

For patients using **Blood Pressure Monitoring** solutions, the weighted average reduction in SBP for digital solution users over the usual care arm was 3.4 mm Hg across all comparative studies in this approach. Using this difference, the PCE calculated annualized cardiovascular disease event risk between the digital solution and usual care arm differed by 0.05% in commercially insured and Medicaid patients, and 0.09% in Medicare beneficiaries. As a result, average annual cardiovascular event spending per patient for the digital solution was less than usual care by $35 in a commercial plan, $25 in Medicare, and $11 in Medicaid (see Exhibit 20).

For patients using **Medication Management** solutions, the weighted average reduction in SBP was 7.1 mm Hg for digital solution users over the usual care arm across all comparative studies in this approach. Using this difference, the PCE calculated annualized cardiovascular disease event risk between the digital solution and usual care arm differed by 0.11% in commercially insured patients, 0.19% in Medicare beneficiaries, and 0.10% in Medicaid patients. Average annual cardiovascular event spending per patient for the digital solution was less than usual care by $72 in a commercial plan, $52 in Medicare, and $23 in Medicaid (see Exhibit 20).

For patients using **Behavior Change** solutions, the weighted average reduction in SBP was 1.0 mm Hg for digital solution users over the usual care arm as reported across all comparative studies in this approach. Therefore, PCE calculated annualized cardiovascular disease event risks between the digital solution and usual care arm only differed by 0.02% in commercially insured patients, 0.03% in Medicare beneficiaries, and 0.01% in Medicaid patients. Average annual cardiovascular event spending per patient for the digital solution was less than usual care by $10 in a commercial plan, $7 in Medicare, and $3 in Medicaid (see Exhibit 20).

Health plan–specific costs were derived using standard pricing ratios (see methodology in **Appendix A**).[235, 236] Spending inputs were inflated to 2023 U.S. dollars using the annual Consumer Price Index for medical care.[237]

Exhibit 20

ESTIMATED DIFFERENCE IN ANNUAL CARDIOVASCULAR EVENT RISK AND ASSOCIATED AVERAGE SAVINGS PER PATIENT

Treatment Arm	Weighted Average Reduction in SBP	DIFFERENCE IN ANNUALIZED CVD RISK COMPARED TO USUAL CARE			AVERAGE ANNUAL SPENDING ON CARDIOVASCULAR EVENTS PER PATIENT		
		Commercial	Medicare	Medicaid	Commercial	Medicare	Medicaid
Blood Pressure Monitoring Solutions	–3.4	0.05%	0.09%	0.05%	–$35	–$25	–$11
Medication Management Solutions	–7.1	0.11%	0.19%	0.10%	–$72	–$52	–$23
Behavior Change Solutions	–1.0	0.02%	0.03%	0.01%	–$10	–$7	–$3

Notes: CVD = cardiovascular disease. SBP = systolic blood pressure. Negative numbers represent healthcare savings.

Calculating Cardiovascular Disease Event Costs

Cardiovascular disease event costs were derived by calculating annualized cardiovascular risk differences between digital solution users and usual care patients using the PCE model. The PCE model calculates 10-year cardiovascular disease risk from patient characteristics such as age, gender, race, total and high-density lipoprotein cholesterol levels, treated SBP, and whether patients are diabetic or smokers (see **Appendix A** for detailed inputs into the PCE). This risk difference was then multiplied by payer-specific event costs (stroke, heart attack, heart failure, and coronary heart disease death) over three years.

As an example, for **Blood Pressuring Monitoring** solutions, annualized cardiovascular risk from the PCE was 1.16% for digital solution users and 1.21% for usual care, for a difference in annualized risk of 0.05%. The model also assumed a 10% mortality from cardiovascular disease events each year. This annualized difference in risk was multiplied by the commercial costs for cardiovascular disease events — $55,295 in year 1, $12,346 in year 2, and $11,456 in year 3. The commercial estimated annual cardiovascular disease event costs per person for **Blood Pressure Monitoring** solutions were $643, compared with $671 for usual care in year 1, for an annual savings of $28 with the digital solution. Subsequent year savings were $35 in year 2 and $41 in year 3, resulting in an average annual savings of $35 per commercially insured patient using the digital solution.

Additional Costs

While digital hypertension management solutions may result in savings from reduced cardiovascular disease event risk, they are associated with increased additional costs from office visits, medication use, and money spent on the solution itself.

Annual frequency of office visits for patients receiving digital hypertension management solutions are assumed to be 3.3 visits and 2.8 visits for usual care for each arm across all approaches and plans.[238] The model assumes that after 12 months of the digital hypertension solution, the frequency of office visits for the digital hypertension management solution arm becomes equal to that for usual care. Reimbursement for an office visit is assumed to be $91 per visit on the basis of the Medicare fee schedule.‡[239] Total annual costs of office visits for digital hypertension management solutions are estimated at $539 in commercial insurance, $296 in Medicare, and $207 in Medicaid; for usual care, total annual costs of office visits are estimated at $466 in commercial insurance, $256 in Medicare, and $179 in Medicaid.

Trends in antihypertensive medication utilization were based on data collected by a National Health and Nutrition Examination Survey of adults with stage 2 hypertension.[240] The model assumes trends in medication utilization and the proportion of patients with hypertension using any antihypertensive medication is 59.6% across both arms across all approaches and plans, and assumed to remain constant beyond one year.[241] List drug prices were derived from Redbook and annual spending is estimated at $206 in commercial insurance, $113 in Medicare, and $79 in Medicaid.[242] Data on changes in medication titration as a result of digital hypertension management solutions were limited. Therefore, this model assumes the impact of digital solutions on medication utilization is reflected in the observed SBP improvements for each approach.

‡ CPT code 99213 ($90.88) Established patient office or other outpatient visit, 20–29 minutes. Source: CMS Physician Fee Schedule, accessed May 2024.

Technology Price

To estimate the net health spending impact of digital solutions, the model offsets the price of the digital hypertension management solution from the healthcare savings.

Blood Pressure Monitoring and **Medication Management** solutions are primarily used by healthcare providers and health systems. Providers may be charged a capitated fee for the solution and then bill insurance via the RPM current procedural terminology (CPT) codes that reimburse them for their time spent reviewing patient data. In Medicare, providers can bill a maximum allowed amount of $1,619 annually for RPM services.‡ However, based on Centers for Medicare and Medicaid Services (CMS) utilization code data from 2022, providers are typically billing $725 annually or $60 per month, assuming one month of setup, five months of device supply and monitoring, five months of care management, and six months of additional care management.[243] Annual billing for RPM is estimated at $1,319 in commercial coverage and $507 in Medicaid.

For **Behavior Change** solutions typically sold directly to employers and health plans, published pricing information was used to estimate an average monthly solution price of $39 per user per month or $468 per user per year, with no variation across plan type.[244]

Actual prices charged by specific solution vendors or negotiated by particular purchasers may vary and would impact these results. Usual care cost was estimated as the cost for in-person blood pressure monitoring via an unconnected blood pressure cuff monitor, at a one-time cost of $32.[245] Some digital hypertension management solutions provide users with connected blood pressure monitors as part of their pricing models or reimburse for the cuff through the RPM codes.

Medicare and Medicaid Coverage Landscape

Hypertension is by far the most common diagnosis for individuals receiving RPM services.[246] In addition to RPM services, Medicare and most states and commercial payers reimburse for self-measured blood pressure (SMBP) services. While SMBP codes were established specifically for blood pressure monitoring outside physician offices, they are significantly underutilized and reimbursed at much lower rates than RPM codes.[247] SMBP monitoring devices are excluded from the list of durable medical equipment that Medicare Part B covers, except for people undergoing dialysis in the home.[248]

CMS SMBP codes cover initial device set up and patient education/training, and data monitoring.[249]

- 99473 ($14.31) — Initial set up and patient education/training on equipment (one-time fee).
- 99474 ($16.64) — Two SMBP readings one minute apart, twice daily, collection of data reported by the patient/caregiver to the physician/qualified healthcare professional; every 30 days (minimum of 12 readings).

CMS remote physiological monitoring codes cover initial device set up and patient education, daily recordings, and treatment and management services.[250]

- 99453 ($19.65) — Initial set up and patient education on equipment (one-time fee).
- 99454 ($46.83) — Remote physiological monitoring device(s) supply with daily recording(s) or programmed alert(s) transmission; every 30 days.
- 99457 ($48.14) — Remote physiological monitoring management services, physician/other qualified healthcare professional time requiring interactive communication with the patient/caregiver during the calendar month; first 20 minutes, every 30 days.
- 99458 ($38.64) — Remote physiological monitoring management services, physician/other qualified healthcare professional time requiring interactive communication with the patient/caregiver during the calendar month; additional 20 minutes, can be billed multiple times in a 30-day period.

While CMS restricts the frequency that providers may bill a certain code each calendar month, current RPM policy allows these codes to be billed indefinitely. However, research finds that most hypertension medication adjustments occur within the first four months of RPM use.[251]

‡ CPT code 99453 ($19.65) One time set up fee; CPT code 99454 ($46.83) Monthly data collection; CPT code 99457 ($48.14) First 20 minutes of care management; CPT code 99458 ($38.64) Additional 20 minutes of care management. Source: CMS Physician Fee Schedule, accessed May 2024.

Change in Overall Spending

Within the three-year time horizon of this budget impact model, digital hypertension management solutions are found to increase total health spending across all approaches and plans because the cost of the solution exceeds the savings from improved clinical outcomes. The cost increases to pay for the digital solutions or RPM billing occur only in year 1 and then produce healthcare savings over the next decade by preventing cardiovascular events.

Private payers who are unlikely to recoup savings over a 10-year window would need to accept the increased costs of these solutions in exchange for the long-term health benefits they deliver. The sections below show the initial increase in health spending over three years for all digital solutions and describe how for Medicare, the **Medication Management** solutions may generate sufficient clinical benefits to offset their spending over 10 years.

Three-Year Spending Impact

For **Blood Pressure Monitoring** solutions (see Exhibit 21), assuming 25% participation, the three-year net health spending increase for a one million-member plan would be $57 million in the commercial market, $62 million in Medicare, and $14 million in Medicaid.

By comparison, while RPM billing is the same, health savings are slightly higher for **Medication Management** solutions that deliver larger reductions in SBP. For these solutions, the three-year net health spending increase for a one million-member plan would be $52 million in the commercial market, $54 million in Medicare, and $13 million in Medicaid.

With a lower monthly solution cost, the total spending increase for **Behavior Change** solutions is lower, but so are the associated health benefits. For these solutions, the three-year net health spending increase for a one million-member plan would be $22 million in commercial, $43 million in Medicare, and $13 million in Medicaid.

Exhibit 21 also shows the cost per user of the digital solution and the estimated increase in cost for every member enrolled in the plan.

Exhibit 21

ESTIMATED CHANGE IN ANNUAL HEALTHCARE SPENDING ON SOLUTIONS

BLOOD PRESSURE MONITORING

	Commercial				Medicare				Medicaid			
	Year 1	Year 2	Year 3	Three-Year Total	Year 1	Year 2	Year 3	Three-Year Total	Year 1	Year 2	Year 3	Three-Year Total
Total Per 1M Members	+$60.7M	–$1.6M	–$1.8M	+$57.3M	+$67M	–$2.4M	–$2.8M	+$61.9M	+$14.6M	–$0.32M	–$0.38M	+$13.9M
Per User Per Year	+$1,332	–$35	–$40	+$419	+$712	–$25	–$29	+$219	+$495	–$11	–$13	+$157
Per Member Per Month	+$5.06	–$0.13	–$0.15	+$1.59	+$5.59	–$0.20	–$0.23	+$1.72	+$1.22	–$0.03	–$0.03	+$0.39

MEDICATION MANAGEMENT

	Commercial				Medicare				Medicaid			
	Year 1	Year 2	Year 3	Three-Year Total	Year 1	Year 2	Year 3	Three-Year Total	Year 1	Year 2	Year 3	Three-Year Total
Total Per 1M Members	+$59.3M	–$3.3M	–$3.8M	+$52.2M	+$64.9M	–$4.9M	–$5.8M	+$54.2M	+$14.3M	–$0.67M	–$0.78M	+$12.9M
Per User Per Year	+$1,302	–$72	–$84	+$382	+$690	–$53	–$61	+$192	+$485	–$23	–$26	+$145
Per Member Per Month	+$4.94	–$0.27	–$0.32	+$1.45	+$5.41	–$0.41	–$0.48	+$1.51	+$1.19	–$0.06	–$0.06	+$0.36

BEHAVIOR CHANGE

	Commercial				Medicare				Medicaid			
	Year 1	Year 2	Year 3	Three-Year Total	Year 1	Year 2	Year 3	Three-Year Total	Year 1	Year 2	Year 3	Three-Year Total
Total Per 1M Members	+$22.8M	–$0.47M	–$0.54M	+$21.8M	+$44.3M	–$0.70M	–$0.82M	+$42.7M	+$13.6M	–$0.09M	–$0.11M	+$13.4M
Per User Per Year	+$501	–$10	–$12	+$160	+$470	–$7	–$9	+$151	+$462	–$3	–$4	+$152
Per Member Per Month	+$1.90	–$0.04	–$0.05	+$0.61	+$3.69	–$0.06	–$0.07	+$1.19	+$1.13	–$0.01	–$0.01	+$0.37

Notes: Assuming 25% of eligible people shift to digital hypertension management solutions from usual care. Negative numbers represent healthcare savings and positive numbers represent healthcare spending.

Long-Term Benefits

Improvements in blood pressure from digital solutions can result in long-term benefits that reduce patients' risk of cardiovascular disease events and deaths. The budget impact model was used to estimate the number of cardiovascular events and associated healthcare cost that could be avoided from using digital hypertension management solutions. It also estimates the number of deaths that would be avoided over the 10-year window by improving hypertension control.

Looking at Medicare (see Exhibit 22), assuming a 25% uptake in a one million-member plan, the model estimates over a 10-year period that:

- For **Blood Pressure Monitoring** solutions, an estimated 850 cardiovascular disease events and 83 deaths could be avoided. Total costs avoided are estimated to be $64 million.
- For **Medication Management** solutions, an estimated 1,764 cardiovascular disease events and 172 deaths could be avoided. Total costs avoided are estimated to be $133 million.
- For **Behavior Change** solutions, an estimated 251 cardiovascular disease events and 24 deaths could be avoided. Total costs avoided are estimated to be $19 million.

Given the substantive clinical benefits in **Medication Management** solutions that result in a greater reduction of cardiovascular events and deaths, we think that targeted investment in these solutions is warranted. For example, if Medication Management solutions can reduce SBP by 9.1 mm Hg relative to usual care, then they would start to

Exhibit 22

ESTIMATED AVOIDED CARDIOVASCULAR DISEASE EVENTS, DEATHS, AND COSTS OVER 10 YEARS IN MEDICARE COVERAGE

	Blood Pressure Monitoring	Medication Management	Behavior Change
Total Events Avoided	**850**	**1,764**	**251**
Heart Attack	309	642	91
Stroke	319	662	94
Heart Failure	222	461	66
Total Deaths Avoided	**83**	**172**	**24**
Total Costs Avoided	**$64.2M**	**$133.3M**	**$18.9M**

achieve budget neutrality within 10 years for Medicare beneficiaries. A key to effective contracting for these solutions will be to ensure that negotiated prices are tied to attainment of promised improvements in blood pressure that are able to be sustained over time.

Patient Out-of-Pocket Costs

Patient out-of-pocket spending for RPM solutions can vary depending on the individual's insurance and plan benefit design. For most patients, solutions that rely on RPM codes for billing will modestly increase their cost-sharing responsibility. Traditional Medicare typically covers 80% of the approved amount for RPM services after the deductible, resulting in a 20% coinsurance for patients; some patients may have supplemental insurance or dual eligibility and may not bear this cost directly. Commercial enrollees will generally pay more for RPM services in the deductible and under coinsurance; those with copay plans may not experience any increase in out-of-pocket costs. In most cases, **Behavior Change** solutions that are purchased directly by a health plan or employer are typically offered to users without any cost-sharing requirement.

Budget Model Limitations

A key assumption in the model is that changes in SBP identified in clinical studies would be sustained throughout the three-year time horizon; however, in reality, blood pressure can improve or regress. Therefore, the risk of cardiovascular events may be over- or underestimated in the model. Additionally, the model assumes an annual, linear risk of cardiovascular events occurring on the basis of the 10-year estimates produced by the PCE algorithm. While this assumption was substantiated by patterns observed in other long-term studies,[252–254] the PCE itself does not estimate one- and three-year risks. Additionally, the model assumes that SBP data from the clinical studies are equal across plans, when in reality, the performance of the digital solution is likely to have varying impact across different types of health plans.

This model uses the PCE as it is a widely used and clinically recognized algorithm recommended by the ACC and AHA to estimate the long-term risk of events. The PCE algorithm accounts for such patient demographics as race, gender, and age — all of which are significant factors in estimating baseline risks of cardiovascular disease. However, other methods have been used in the literature to calculate cardiovascular disease event risk. One study conducted using AMC Health's solution used the HealthPartners Institute Model Health: Cardiovascular Disease microsimulation model based off the Framingham Heart Study to extrapolate predicted cardiovascular disease events on the basis of observed improvements in SBP in the study. The microsimulation model included effects on additional cardiovascular disease risk factors besides SBP, such as weight and previous cardiovascular disease history, but did not factor in race as a variable.[255] A separate analysis conducted by Teladoc linked blood pressure readings to risk of cardiovascular disease events and costs. The model utilized methodology from Song et al. to assume a 10 mm Hg decrease in blood pressure resulted in a 32% and 45% risk reduction in heart attack and stroke. However, the method used in Song et al. to estimate risk reduction uses a single estimate for incidence of heart attack and stroke and does not account for changes in age, which is an influential characteristic in predicting cardiovascular disease risk.[256]

Another limitation of this model is that medication use is assumed to be equal and remain constant over the years between patients that use digital hypertension management solutions and usual care. The benefits of higher medication use are assumed to be reflected in the improvements in SBP and, therefore, attributing to improvements in cardiovascular disease event risk. In addition, for **Medication Management** solutions, the model does not assume alternate billing for clinical pharmacists or care teams who may monitor patient data and adjust medication therapy that could result in potential decreased costs.

This economic analysis does not account for loss of workplace productivity related to hypertension. However, as one of the most common prevalent chronic conditions, hypertension is associated with absenteeism, reduced productivity, and short-term disability resulting in indirect costs attributable to lost workplace productivity. One model estimated 0.45 more hours absent from work over two weeks (absenteeism) and 0.18 more hours lost while at work over two weeks (presenteeism) for employees with hypertension compared with employees without hypertension.[257] If digital solutions can result in improved outcomes due to more effective and convenient hypertension management care, then there is potential for greater cost savings.

Scenario Analysis

Since SMBP codes are reimbursed at a much lower cost than RPM codes, there is little incentive for digital solution companies to enable use of SMBP codes and for providers to bill them, leading to underutilization. However, if SMBP codes were more widely used, it would result in more favorable net health spending for digital hypertension management solutions. A scenario analysis was conducted to estimate the budget impact of **Blood Pressure Monitoring** solutions assuming providers bill the maximum Medicare–allowed amount of $214 annually for SMBP services, which includes one month of set up and 12 months of SMBP data monitoring.[258] Annual billing for SMBP was estimated at $389 in commercial coverage and $150 in Medicaid.

Assuming a 25% uptake in a one million-member plan, the three-year net health spending increase would be $18 million in the commercial market, $19 million in Medicare, and $4 million in Medicaid. **Blood Pressure Monitoring** solutions would achieve budget neutrality by year 9 in Medicare. Greater incentives to drive billing of SMBP codes over RPM codes could result in more favorable economic benefits within a 10-year timeframe for digital solutions.

Solution-Specific Economic Findings

The evaluation of the economic evidence examined 26 articles that included information about the impacts of digital hypertension management solutions on costs of care and healthcare resource utilization. The articles were identified through the structured literature search described above and through direct submissions from companies. A total of 12 articles contained sufficient detail to evaluate the economic results and are described below. Articles published prior to 2014 fell outside the review timeframe and were excluded. See **Appendix B-3** for a list of articles.

Overall, the methodological rigor of these studies varied significantly, making our extrapolation of the results challenging. Some of the reports did not use study data to determine cost of care, and most used comparator groups that consisted of nonusers or propensity-matched cohorts. Many of the studies did not report or include direct program costs of the digital solution and, therefore, did not indicate if reported gross savings offset the cost of the solution.

As a result, company reported savings from the solutions varied widely, but generally estimated far higher savings than what is predicted in the budget model. More research is needed on the long-term cost implications of digital hypertension solutions and whether the potential savings attributable to incremental health benefits from improved BPC fully offset the increased spending on the digital solution over time.

AMC Health

A follow-up analysis of the AMC Hyperlink randomized controlled trial reported on cardiovascular events and costs at five years for patients who received a digital hypertension management solution versus usual care. The 2020 study reported 10 patients had cardiovascular events in the digital solution group versus 19 patients in the usual care group. A microsimulation using Medicare Expenditure Panel Survey data estimated total five-year cardiovascular event costs for the digital solution group were $2,772 per patient compared with $5,721 for usual care. Assuming direct program costs of $1,511 per patient for the digital solution, a net savings of $24 per month would result if savings were spread evenly over the five-year period.[259]

Cadence

A difference in difference analysis using accountable care organization claims data from 2019 to 2023 compared enrolled patients in Cadence's virtual hypertension program to those who were prescribed Cadence but did not enroll. Reported gross savings was $157 per member per month over five years. Cost of the solution and net savings were not reported. Prior to Cadence enrollment, the Cadence enrollees had costs twice as high as the costs of patients that did not enroll in Cadence, indicating differences in population that may be driving savings.[260]

Hello Heart

A 2021 Validation Institute review of the Hello Heart solution — updated in 2023 — compared medical claims data of users of the digital solution with a matched cohort of patients who did not use it, but provided little detail on how the matching of controls in this study was conducted. The review found that use of the solution was associated with gross savings of $199 per user per month from cardiovascular disease costs, representing a 19% reduction in total medical spending per user per year. The cost of the digital solution was not reported and, therefore, net savings could not be estimated. Differences in costs were mostly driven by lower utilization of surgery and inpatient care.[261]

Teladoc (Livongo)

A 2020 study used propensity score matching paired with a difference-in-difference analysis to estimate impacts on medical spending from the hypertension solution developed by Teladoc. Results from the study suggested gross medical savings of $81 per member per month, on the basis of a 19% difference in medical spending between participants and nonparticipants. Cost of the solution and net savings were not reported. Medical savings included $9 per member per month for decreased emergency room visits and $29 per member per month from lower inpatient admissions.[262]

A 2019 company analysis estimated three-year cost savings from reduced cardiovascular disease events and other healthcare utilization among Teladoc users. The analysis used assumptions from other models and national incidence rates of heart attack, stroke, and hypertension-related emergency department visits to extrapolate event risk reductions from population-level improvements in SBP among patients in the hypertension program. The model also assumed two fewer office visits annually, as observed from the Teladoc diabetes program. Projected savings for the program was estimated at $58 per participant per month, or a net savings of $19 per member per month (assuming program costs of $39 per member per month).[263] A follow-up case study by Teladoc looking at patients of Harris Health System in 2020 built off this analysis and estimated a gross savings of $77 per member per month.[264]

Ochsner Digital Medicine

A company analysis conducted in 2021 and reviewed by the Validation Institute in 2023 evaluated members of a Medicare Advantage plan, Medicare Shared Savings Program plan, and employer health plan who were enrolled in Ochsner Digital Medicine's chronic disease program from 2017 to 2019. The study propensity matched participants in the program to controls and estimated the total medical and pharmacy costs for the first three years of the program. Ochsner Digital Medicine program participants had increased savings of $204 per member per month compared with controls in the first year. However, in subsequent years, members in the Ochsner employer plan showed increased costs of $303 more per member per month in year 2 and $48 more per member per month in year 3 relative to controls. Whereas those in Ochsner's Medicare Advantage and Medicare Shared Savings Program plans had savings of $311 and $168, respectively, in year 2 and $355 and $196 in year 3. Cost of the digital solution program were not reported and net savings for each plan could not be estimated. For the Medicare Advantage plan, the digital solution group had reduced office visits by 29% in year 1, 19% in year 2, and 25% in year 3. In contrast, both the Medicare Shared Savings Program and employer plans saw increases in in-office visits for the digital solution group relative to usual care — by 5% and 14%, respectively, in year 1; 15% and 59% in year 2; and 9% and 19% in year 3.[265, 266]

Omada

A 2024 study evaluated members of Omada's virtual care programs and propensity matched them to patient records from a separate National Health and Nutrition Examination Survey study to extrapolate reductions in weight loss, HbA1c, and blood pressure levels over a five-year period. It also simulated potential benefits and associated savings from the virtual care programs. The model, which is reported in 2022 dollars, projected gross medical savings of $76 per member per month from the hypertension program after the first year, with no reported cost of the program. Sustained improvements could increase saving to $87 per member per month spread evenly over a five-year period.[267]

VitalSight

Three comparative studies that used VitalSight's digital hypertension management solution analyzed the impact of the solution on healthcare resource utilization.[268–270] Overall, the studies found that use of the digital solution is associated with reductions in physician office visits, but net increases in number of encounters across all modalities, including tele-health, in-person visits, patient portal interactions, and telephone counseling. Patients who used the digital solution also showed increased use of antihypertensive medications compared with usual care.

Summary Ratings

Based on PHTI's review of clinical evidence, one approach — **Medication Management** — provides clinically meaningful and more rapid declines in SBP compared with usual care (see Exhibit 23). **Blood Pressure Monitoring** shows slightly greater, but not clinically meaningful declines in SBP compared with usual care; this may improve if care teams take consistent action based upon patient data (e.g. medication adjustments).

This report found that over the three-year time horizon, all approaches across all payer types (Medicare, commercial, and Medicaid) increase total healthcare spending, because the cost of the solution exceeds the savings from improved clinical outcomes. However, given that data from the reviewed clinical studies show improved SBP from some digital hypertension management approaches compared with usual care, these solutions may reduce some healthcare costs over a longer period.

The evidence suggests that by delivering regular home monitoring of blood pressure, often accompanied by clinician notifications and recommendations, solutions using the **Blood Pressure Monitoring** approach produce slightly greater SBP declines compared with usual care. However, savings from these health improvements are not sufficient to offset the increased costs associated with current provider reimbursement rates through RPM codes during the three-year budget period.

By outsourcing medication management to dedicated, virtual care teams, solutions using the **Medication Management** approach deliver clinically meaningful benefits compared with usual care. Solutions using this approach generally resulted in more rapid and steeper declines in SBP and considerable improvements in the number of patients achieving BPC compared with what most providers can achieve with in-person visits. Because hypertension risks accrue over the long term, these solutions increase net spending in the three-year budget window but may offset long-term healthcare costs due to savings from avoided cardiovascular events.

The **Behavior Change** approach generally delivers limited incremental declines in SBP compared with usual care but may have potential for underserved populations with limited access to usual care. By supporting patient hypertension self-management and education, these solutions may help close access and equity gaps in traditional care models.

The best opportunity for performance in this area may be a combined approach that includes monitoring, medication management, and patient education. Furthermore, targeting solutions to underserved patients who do not have regular access to usual care may help maximize healthcare benefits and cost savings.

Exhibit 23

PHTI RATINGS BY DIGITAL HYPERTENSION MANAGEMENT APPROACH

● Positive ● Moderate ● Negative
● Higher Clinical Evidence Certainty ○ Lower Clinical Evidence Certainty

Approach	Clinical Effectiveness[a]	Economic Impact	Summary Rating[b]
Blood Pressure Monitoring AMC Health HRS VitalSight	● **Results:** Slightly greater, but not clinically meaningful declines in SBP compared with usual care **Evidence Certainty:** Higher	● Increases net health spending at current RPM reimbursement rates	● **Evidence may support adoption for providers who consistently act on monitoring data**
Medication Management Cadence Ochsner Digital Medicine Story Health	● **Results:** Clinically meaningful and more rapid declines in SBP compared with usual care **Evidence Certainty:** Higher	● Increases net health spending initially, with potential to offset costs over the long-term because of savings from avoided cardiovascular events	● **Evidence supports broader adoption due to clinical benefits, potential long-term savings, and improvements to population health**
Behavior Change Dario Hello Heart Lark Omada Teladoc (Livongo)	○ **Results:** Limited incremental declines in SBP compared with usual care **Evidence Certainty:** Lower	● Increases net health spending because limited health improvements do not offset solution price	● **Current evidence does not support broader adoption for most patients**

Source: PHTI, Digital Hypertension Management Solutions Assessment, October 2024. See PHTI.org for complete report, methods, and recommendations.

Notes: SBP = systolic blood pressure. RPM = remote patient monitoring. [a] Not all solutions have clinical data that meet the inclusion standards for this report. Based on the similarity of approaches, it is fair to assume that companies without solution-specific data perform in line with the category. Purchasers and users will have to make their own assumptions about performance. [b] Summary rating reflects the combination of clinical and economic results.

Next Steps

Realizing Full Potential of Digital Hypertension Management Solutions

Achieving and maintaining hypertension control is a national priority. Yet, over the past decade, key indicators of hypertension progress have worsened. This is alarming because hypertension is a broad indicator of the health of a population as it ages. In this context, digital hypertension management solutions have an important role to play in helping patients lower their blood pressure and improve their long-term cardiovascular health.

The findings of this report present two areas of next steps: (1) improving the clinical impact of digital health solutions by integrating the most effective components of existing solutions, and (2) aligning payment models with long-term spending and benefits of hypertension management.

Recommendations for Innovators

Integrate the Best of Existing Solutions

All three categories of digital hypertension management solutions demonstrate some clinical benefit to patients; however, goal-driven medication management should be a part of any digital solution. Particularly for specific patient populations, combining medication management with patient education and self-management support may help close access gaps in traditional care models.

Whereas **Blood Pressure Monitoring** approaches (often billed as RPM solutions) may facilitate medication management with a patients' clinical team, these solutions do not ensure that it happens. Rapid and effective medication management requires collaboration with licensed prescribers who are focusing on medication adherence, the right combination of prescription drugs, and medication titration toward a blood pressure goal, while actively monitoring side effects. Centralizing these functions within the digital solutions yields better results and reduces the variability in what type of care a patient may otherwise receive.

If a solution integrates both a data-driven approach and medication management, the evidence from the **Behavior Change** approach indicates that certain patient populations — particularly those with low health literacy, of low socioeconomic status, and historically underserved or marginalized in usual care — require enhanced support to engage successfully in this process. Given the importance of achieving health equity in hypertension outcomes, the ability to deploy tailored behavior change support for specific patients is likely to be an important part of an effective solution.

Advance the Evidence Base

While the clinical evidence for digital hypertension management solutions is relatively robust, important questions remain. The long-term impact of digital hypertension management solutions on clinical outcomes and healthcare utilization needs to be studied.

Do patients sustain improvements in hypertension over time? For how long?

Much of the evidence tracks patients for 6–12 months, leaving open questions about whether patients can sustain their hypertension improvements. Given the significance of hypertension and it's impact on 10-year mortality, it is important to understand how these health benefits change over a decade.

How do digital hypertension management solutions change healthcare utilization?

Current evidence finds that most digital solutions increase the frequency of primary care visits, as patients receive more data feedback and have questions about their care. **Medication Management** solutions could improve their economic impact if virtual medication management teams could replace a subset of in-person primary care visits.

Recommendations for Providers

Integrate Digital Medication Management into Usual Care and Other Digital Hypertension Management Solution Types

As effective digital hypertension management solutions scale in terms of users and payment volumes, they must evolve to accept accountability for delivering clinical results. Achieving this goal requires viewing hypertension as part of a patient's overall clinical profile, which includes medication optimization (including deprescribing, as needed), defining and adjusting hypertension goals on the basis of other health conditions, and engaging with a patient longitudinally to ensure that short-term impacts are sustained to accrue material reductions in cardiovascular risk over a longer period. Practically, this means that digital hypertension management solutions should not be seen as separate from usual care. Instead, digital hypertension management solutions, should become more integrated with primary care systems over time.

The most pressing area of integration with usual care is in medication management. Digital hypertension solutions can excel by adding process discipline and by supplementing the labor force (e.g., clinical pharmacists) within usual care settings. For provider practices that do not have a dedicated focus on hypertension or have resource constraints, these solutions can be a helpful supplement to clinical practice.

The degree of integration between digital hypertension management solutions and usual care has a direct impact on the ultimate value of digital solutions. If digital hypertension management solutions result in better outcomes for patients while reducing the load on usual care (e.g., fewer primary care visits to adjust medications or address side effects), they will be able to demonstrate a much higher economic impact profile. However, achieving this impact requires collaboration on clinical and operational workflow efficiency to unlock economic value.

Recommendations for Purchasers

Recognize Existing Financial Opportunities

Increased public health and healthcare focus on hypertension management control supports broader investments in prevention, diagnosis, and effective treatment, which stand to make people healthier and reduce overall societal healthcare spending. Unfortunately, enrollee churn averages three years or less in most insurance markets, so payers who invest in hypertension management are unlikely to reap the economic benefits from members' avoided cardiovascular events over the long term. As such, financial incentives for improved hypertension management need to be reconsidered.

In the commercial market, employers and health plans are likely to make investments in hypertension health, even if they increase short-term budgets — because the clinical benefits are clear. Nonetheless, these payers should make careful purchasing choices to select digital solutions or other interventions that deliver the greatest clinical benefits. That may include the **Medication Management** solutions discussed in this report or other enhancements to in-person primary care services. They should also use outcome-based contracts that link meaningful clinical performance to payment, ensuring that added investments in hypertension are achieving their aims for blood pressure improvements.

The Medicare program does benefit from long-term improvements in hypertension outcomes, though individual Medicare Advantage (MA) plans face similar enrollee churn challenges as the commercial market.

As such, the MA program uses quality measures to encourage investments in chronic disease management for members, including hypertension. Plans translate these metrics — which are tied to considerable bonus payments — into gap closure programs that are operational, rather than clinical, in nature. For instance, medication adherence for hypertension and BPC both contribute to MA Star Ratings.In 2024, the BPC measure — drawn from the HEDIS measure set used by a wider set of purchasers — became triple-weighted in the MA program. Plans should respond to the increased financial benefits of these measures by increasing their per member per month investment in hypertension control programs. In addition, given the clinical efficacy and long-term positive budget impacts, particularly for Medicare, policymakers should explore innovative mechanisms to promote deployment of these tools broadly. For example, this might include funding for public health interventions or community benefit programming to help deploy these digital tools in culturally competent ways within hard to reach populations.

For providers, their investments in hypertension management programs can increase revenue (through RPM billing) in fee-for-service environments. Given the evidence that most medication adjustments using RPM occur in the first four months, purchasers could consider reimbursement policies that limit the duration of billing or encourage medication management. Providers participating in value-based payment programs may also benefit from higher payments for improved hypertension management and control.

Each purchaser should complete their own analysis of the aggregate upside and downside associated with hypertension management — beyond direct costs and savings in the budget model. These analyses must consider the patients, members, or employees to whom they are accountable. Estimates should be reviewed annually, especially as new quality incentives or measure sets become available.

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All Studies with BPC Outcomes

To access all appendices, please visit https://phti.org/assessment/digital-hypertension-management-solutions/#appendices.

Online Data Supplement

Access the online data supplement here.

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