American Heart Association.

AMA AMERICAN MEDICAL ASSOCIATION

1150 Connecticut Ave., NW | Suite 300 | Washington, DC 20036
P 202-785-7900 | F 202-785-7950 | www.heart.org

330 N. Wabash Avenue | Suite 39300 | Chicago, IL 60611-5885
P 312-464-5000 | F 312-464-4184 | www.ama-assn.org

October 23, 2020

Tamara Syrek Jensen
Director
Coverage and Analysis Group
U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Formal Request for a National Coverage Determination

Dear Director Jensen:

On behalf of the America Heart Association and the American Medical Association, we are submitting a formal request for a national coverage determination (NCD) for validated home blood pressure (BP) measurement devices for use with self-measured BP (SMBP) monitoring through Medicare. This request is for the benefit category of durable medical equipment and is submitted under Track #1, "Request for New National Coverage Determination Initiated by any Party, Including Beneficiaries, Manufacturers, Providers or Suppliers." As detailed in the attached request, we believe that coverage of SMBP monitoring is "reasonable and necessary" as defined under the Medicare statute. The Medicare population experiences high rates of hypertension, and strong evidence supports the use of SMBP monitoring to enable patients and their doctors to effectively treat and manage hypertension.

Cardiovascular disease (CVD) indicates a class of diseases that includes heart disease, stroke, and heart failure.[1] Heart disease and stroke represent the first and fifth leading causes of death in the U.S., respectively, and can result in significant disability and diminished quality of life. Hypertension is a major modifiable risk factor for these diseases. In 2017-2018, 45.4 percent of U.S. adults had hypertension, including 74.5 percent of older adults.[2] Among Medicare fee-for-service beneficiaries aged 65 and older, the prevalence of hypertension is 58.2 percent; the prevalence among Black Medicare beneficiaries 65 and older is even higher, at 71 percent.[3] There are 87 million U.S. adults with hypertension who are

[1] American Heart Association. What is Cardiovascular Disease? https://www.heart.org/en/health-topics/consumer-healthcare/what-is-cardiovascular-disease.

[2] Ostchega Y, Fryar CD, Nwankwo T, Nguyen DT. Hypertension prevalence among adults aged 18 and over: United States, 2017–2018. NCHS Data Brief, no 364. Hyattsville, MD: National Center for Health Statistics. 2020.

[3] Centers for Medicare and Medicaid Services. Chronic Conditions. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/CC_Main.html.

recommended to make lifestyle modifications and take antihypertensive medication based on clinical guidelines. Of these individuals, 71 percent have uncontrolled hypertension.[4] Accordingly, the costs of uncontrolled hypertension are enormous. Costs related to CVD reached $555 billion in 2016.[5] In 2010, Medicare paid 52.8 percent of hypertension treatment costs among those ages 65 and older and accounted for 29.7 percent of all adult hypertension treatment costs.[6]

Fortunately, CVD can be prevented. Pharmacologic management of hypertension, along with certain health behavior changes, could prevent approximately 80 percent of CVD deaths.[7] Regular monitoring of BP is key to effective treatment. SMBP monitoring enables patients to collect BP measurements at home outside of the office and report these measurements to their provider. Frequent SMBP monitoring facilitates better tracking of BP over time, which supports BP management and can help reduce one's risk of serious and costly diseases such as heart failure and chronic kidney disease.[8]

The need for Medicare coverage of SMBP devices is long-standing, given the importance of BP monitoring and the numerous barriers to medical care that Medicare beneficiaries face. However, the COVID-19 pandemic has added greater urgency, creating an unprecedented need for out-of-office home-based care as patients are following stay-at-home and social distancing recommendations, and have less in-person access to their physicians. Two new Current Procedural Terminology® (CPT®) codes became available in January 2020 that physicians and other health professionals may use to educate patients about SMBP monitoring and review data collected via SMBP monitoring for use in patient treatment plans (99473 and 99474). These services can also assist in clinician management of hypertension through telehealth visits, and Medicare coverage of telehealth services has been greatly expanded during the COVID-19 public health emergency.[9] The Administration has proposed making many newly covered telehealth services available to Medicare patients permanently.[10] Our organizations strongly support making expanded telehealth coverage permanent nationwide.

By providing coverage of SMBP devices in Medicare, CMS has the opportunity to equip patients with critical tools to help manage hypertension. The following request for an NCD provides full documentation of the benefits and need for SMBP device coverage in Medicare. In this request, we provide both an overview of the issues surrounding hypertension, its prevalence among Medicare beneficiaries, impacts on the population at-large, and concerns regarding standard diagnosis and

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[4] Ritchey MD, Gillespie C, Wozniak G, et al. Potential need for expanded pharmacologic treatment and lifestyle modification services under the 2017 ACC/AHA Hypertension Guideline. *Journal of clinical hypertension (Greenwich, Conn).* 2018;20(10):1377-1391.

[5] Id.

[6] Davis, K. Expenditures for Hypertension among Adults Age 18 and Older, 2010: Estimates for the U.S. Civilian Noninstitutionalized Population. Statistical Brief #404. April 2013. Agency for Healthcare Research and Quality, Rockville, MD. meps.ahrq.gov/mepsweb/data_files/publications/st404/stat404.shtml.

[7] Id.

[8] American Heart Association. Monitoring at home yields better blood pressure control American Heart Association Meeting Report - Presentation P351. 2018. At: https://newsroom.heart.org/news/monitoring-at-home-yields-better-blood-pressure-control.

[9] Centers for Medicare and Medicaid Services. Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19. April 29, 2020. https://www.cms.gov/files/document/covid-19-physicians-and-practitioners.pdf.

[10] Trump Administration Proposes to Expand Telehealth Benefits Permanently for Medicare Beneficiaries Beyond the COVID-19 Public Health Emergency and Advances Access to Care in Rural Areas [press release] CMS Newsroom. Aug 03, 2020. At: https://www.cms.gov/newsroom/press-releases/trump-administration-proposes-expand-telehealth-benefits-permanently-medicare-beneficiaries-beyond.

treatment. We then lay out the evidence that SMBP monitoring using SMBP devices can improve hypertension control. In light of the impact that COVID-19 has had on patient care along with longstanding access concerns, we also highlight the important role that SMBP monitoring can play in telehealth care for hypertension. The positive effects of SMBP monitoring will provide public health benefits and promote health equity among the millions of Americans with hypertension at high risk of heart disease and stroke.

Thank you for considering this request. Should you have any questions or comments, please contact Margaret Garikes, Vice President, Federal Affairs at the AMA, at margaret.garikes@ama-assn.org or (202) 789-7409 or Katie Bishop Kendrick, Senior Policy Analyst at AHA, at katie.bishopkendrick@heart.org or (401) 339-3608.

Sincerely,

American Heart Association
Chief Executive Officer
American Heart Association

James L. Madara, MD
Executive Vice President, CEO
American Medical Association

Formal Request for an NCD Consideration

Hypertension is a major modifiable risk factor for cardiovascular diseases including heart disease, stroke, and heart failure.[11] However, uncontrolled hypertension remains a significant public health issue.[12,13] The American Heart Association (AHA) defines hypertension or high blood pressure (BP) in adults ≥20 years of age as having systolic BP (SBP) ≥130 mm Hg, diastolic BP (DBP) ≥80 mm Hg, or taking antihypertensive medicine.[14] The Centers for Medicare & Medicaid Services (CMS) has called hypertension "the most important modifiable risk factor for coronary heart disease… stroke… congestive heart failure, and end-stage renal disease."[15] Nearly half (45.4 percent) of U.S. adults had hypertension as of 2017, including 74.5 percent of older adults.[16] Hypertension prevalence increases with age and varies by race. [17] Among Medicare beneficiaries age 65 and older, 58.2 percent had hypertension including 71 percent of Black Medicare beneficiaries.[18] Less than half (29 percent) of those with hypertension had hypertension control (office SBP <140 mm Hg and office DBP <90 mm Hg) according to the most recent data.[19] Troublingly, after years of improvement, rates of BP control have declined in recent years, with rates in 2017-2018 matching those of 2005-2006.[20] Uncontrolled hypertension can lead to serious adverse health effects.

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[11] American Heart Association. What is Cardiovascular Disease? https://www.heart.org/en/health-topics/consumer-healthcare/what-is-cardiovascular-disease.

[12] Whelton PK, Carey RM, Aronow WS, Casey DE, Jr., Collins KJ, Dennison Himmelfarb C, DePalma SM, Gidding S, Jamerson KA, Jones DW, MacLaughlin EJ, Muntner P, Ovbiagele B, Smith SC, Jr., Spencer CC, Stafford RS, Taler SJ, Thomas RJ, Williams KA, Sr., Williamson JD, Wright JT, Jr. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Hypertension. 2018; 71:e13-e115.

[13] Curfman G, Bauchner H, Greenland P. Treatment and Control of Hypertension in 2020: The Need for Substantial Improvement. JAMA. Published online September 09, 2020. doi:10.1001/jama.2020.13322.

[14] Whelton PK, Carey RM, Aronow WS, Casey DE, Jr., Collins KJ, Dennison Himmelfarb C, DePalma SM, Gidding S, Jamerson KA, Jones DW, MacLaughlin EJ, Muntner P, Ovbiagele B, Smith SC, Jr., Spencer CC, Stafford RS, Taler SJ, Thomas RJ, Williams KA, Sr., Williamson JD, Wright JT, Jr. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Hypertension. 2018; 71:e13-e115.

[15] Centers for Medicare and Medicaid Services. (2015). Hypertension. https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Dwnld-DataSnapshot-Hypertension.pdf.

[16] Ostchega Y, Fryar CD, Nwankwo T, Nguyen DT. Hypertension prevalence among adults aged 18 and over: United States, 2017–2018. NCHS Data Brief, no 364. Hyattsville, MD: National Center for Health Statistics. 2020.

[17] Yechiam Ostchega, Ph.D., R.N., Cheryl D. Fryar, M.S.P.H., Tatiana Nwankwo, M.S., and Duong T. Nguyen, D.O. Hypertension Prevalence Among Adults Aged 18 and Over: United States, 2017–2018. NCHS Data Brief No. 364, April 2020.

[18] Centers for Medicare and Medicaid Services. Chronic Conditions. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/CC_Main.html.

[19] Ritchey MD, Gillespie C, Wozniak G, et al. Potential need for expanded pharmacologic treatment and lifestyle modification services under the 2017 ACC/AHA Hypertension Guideline. *Journal of clinical hypertension (Greenwich, Conn).* 2018;20(10):1377-1391.

[20] Muntner Paul, et al. Trends in Blood Pressure Control Among US Adults With Hypertension, 1999-2000 to 2017-2018. Journal of the American Medical Association. 2020. doi:10.1001/jama.2020.14545.

In addition to its human toll, CVD is enormously costly. Costs related to CVD reached $555 billion in 2016, including $318 billion in direct medical costs and another $237 billion in indirect costs (e.g., lost work productivity);[21] Medicare paid 52.8 percent of these costs among those ages 65 and older and was the largest single payer (29.7 percent) among all adults ages 18 and older in 2010.[22] Costs are expected to rise to $1.1 trillion ($749 billion direct, $368 billion indirect) by 2035.[23] Among all CVD-related expenditures, the second-highest are those related to hypertension; in 2016, the United States spent $68 billion on hypertension and will spend an estimated $154 billion in 2035.[24] Fortunately, CVD can be prevented. Eliminating hypertension could reduce CVD mortality by an estimated 30.4 percent among males and 38.0 percent among females.[25] Among males, this represents a larger impact on CVD mortality than the elimination of all other CVD risk factors; among females, the impact of eliminating hypertension on CVD mortality is second only to smoking cessation.[26]

Measuring BP is an essential component of hypertension treatment and management. BP may be measured in the office or outside of the office, but best practices suggest hypertension management should include BP measurements taken in both settings, as office BP readings can be rendered inaccurate by a variety of phenomena like white-coat hypertension and masked hypertension.[27] BP measurements taken at home also enable patients to take their blood pressure more frequently than office BP measurements allow. Inaccurate and infrequent BP measurements can hinder management and treatment as well as diagnosis, making it harder to identify changes in patient's disease course or response to medications.

Individuals with white-coat hypertension have high in-office BP measurements but do not have high out-of-office BP measurements.[28] Those with masked hypertension do not have high in-office BP measurements but have high out-of-office BP measurements. Individuals with sustained hypertension have high in-office and out-of-office BP measurements, and individuals with sustained normotension have neither high office nor high out-of-office BP measurements. Compared to sustained normotension, white-coat hypertension is associated with a moderate or no increased risk of CVD and mortality, and

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[21] Id.

[22] Davis, K. Expenditures for Hypertension among Adults Age 18 and Older, 2010: Estimates for the U.S. Civilian Noninstitutionalized Population. Statistical Brief #404. April 2013. Agency for Healthcare Research and Quality, Rockville, MD. https://meps.ahrq.gov/data_files/publications/st404/stat404.shtml.

[23] Id.

[24] Id.

[25] Benjamin, E. J., Blaha, M. J., Chiuve, S. E., Cushman, M., Das, S. R., Deo, R., ... & Jiménez, M. C. (2017). Heart disease and stroke statistics-2017 update: a report from the American Heart Association. *Circulation*, *135*(10), e146-e603.

[26] Id.

[27] Whelton PK, Carey RM, Aronow WS, Casey DE, Jr., Collins KJ, Dennison Himmelfarb C, DePalma SM, Gidding S, Jamerson KA, Jones DW, MacLaughlin EJ, Muntner P, Ovbiagele B, Smith SC, Jr., Spencer CC, Stafford RS, Taler SJ, Thomas RJ, Williams KA, Sr., Williamson JD, Wright JT, Jr. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Hypertension. 2018;71:e13-e115.

[28] Alejandro de la Sierra. Definition of White Coat Hypertension Ambulatory Blood Pressure, Self-Measured Blood Pressure, or Both? *Hypertension*. 2013;62:16–17. https://doi.org/10.1161/HYPERTENSIONAHA.113.01565.

lower risk of CVD and mortality than sustained hypertension.[29,30,31] In contrast, compared to sustained normotension, masked hypertension is associated with an increased risk of CVD and mortality, and similar risk of CVD and mortality as sustained hypertension.[32,33,34] An estimated 15-25 percent of adults with elevated office blood pressure readings have white coat hypertension, and about 15-30 percent of adults with non-elevated blood pressure in the office have masked hypertension.[35,36] Blacks have a substantially higher prevalence of masked hypertension.[37] Neither white-coat hypertension nor masked hypertension can be identified using office BP measurements alone. Out-of-office BP readings are essential to identify such patterns, and to ensure that hypertension is accurately diagnosed and managed. Without out-of-office BP measurements, a clinician may assume that all patients with high office BP have hypertension, and all patients without high office BP do not have hypertension. More accurate identification of the presence or absence of hypertension using out-of-office BP measurements can prevent over-treatment (for those with white-coat hypertension) or under-treatment (for those with masked hypertension), hospitalizations, and other costly direct and indirect outcomes; saving not only lives but also important resources for Medicare.[38]

There are two available validated methods of out-of-office BP monitoring. The first is ambulatory BP monitoring (ABPM). In line with the U.S. Preventive Services Task Force (USPSTF) recommendations,[39] ABPM is currently covered by Medicare to confirm a diagnosis of hypertension among individuals with high office BP and exclude a diagnosis of hypertension among individuals without high office BP. Although considered the gold standard of out-of-office BP monitoring, ABPM it is not well-tolerated by

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[29] Shimbo, D. and P. Munter. Should Out-of-Office Monitoring Be Performed for Detecting White Coat Hypertension? *Annals of Internal Medicine.* 2019; 170(10): 890-892. https://doi.org/10.7326/M19-1134.

[30] Cohen JB, Denker MG, Cohen DL, Townsend RR. Cardiovascular Events and Mortality in White Coat Hypertension. *Ann Intern Med*. 2019;171(8):603-604. doi:10.7326/L19-0524.

[31] Briasoulis A, Androulakis E, Palla M, Papageorgiou N, Tousoulis D. White-coat hypertension and cardiovascular events: a meta-analysis. *J Hypertens*. 2016;34(4):593-599. doi:10.1097/HJH.0000000000000832.

[32] Franklin SS, O'Brien E, Thijs L, Asayama K, Staessen JA. Masked hypertension: a phenomenon of measurement. *Hypertension*. 2015;65:16-20.

[33] Pierdomenico SD, Pierdomenico AM, Coccina F, Clement DL, De Buyzere ML, De Bacquer DA, Ben-Dov IZ, Vongpatanasin W, Banegas JR, Ruilope LM, Thijs L, Staessen JA. Prognostic Value of Masked Uncontrolled Hypertension. *Hypertension*. 2018;72:862-869.

[34] Stergiou GS, Asayama K, Thijs L, Kollias A, Niiranen TJ, Hozawa A, Boggia J, Johansson JK, Ohkubo T, Tsuji I, Jula AM, Imai Y, Staessen JA. Prognosis of white-coat and masked hypertension: International database of home blood pressure in relation to cardiovascular outcome. *Hypertension*. 2014;63:675-682.

[35] Carter EJ, Moise N, Alcantara C, Sullivan AM, Kronish IM. Patient Barriers and Facilitators to Ambulatory and Home Blood Pressure Monitoring: A Qualitative Study. *Am J Hypertens*. 2018;31:919-27.

[36] Peacock J, Diaz KM, Viera AJ, Schwartz JE, Shimbo D. Unmasking masked hypertension: prevalence, clinical implications, diagnosis, correlates and future directions. *J Hum Hypertens*. 2014;28(9):521-528. doi:10.1038/jhh.2014.9.

[37] Anstey DE, Booth JN 3rd, Abdalla M, et al. Predicted Atherosclerotic Cardiovascular Disease Risk and Masked Hypertension Among Blacks in the Jackson Heart Study. *Circ Cardiovasc Qual Outcomes*. 2017;10(7):e003421. doi:10.1161/CIRCOUTCOMES.116.003421.

[38] Verughese J, Chattopadhyay SK, Proia KK, et al. Economics of self-measured blood pressure monitoring: a community guide systematic review. *Am J Prev Med*. 2017;53(3):e105-e113.

[39] Id.

some patients and is not widely available in the United States.[40,41] Self-measured blood pressure (SMBP) monitoring, the second method of out-of-office BP measurement, currently involves a patient's measurement of his or her own BP using an automatic or semi-automatic oscillometric BP device (i.e., a SMBP device) along with a BP cuff, outside of the office setting but with the support of a clinical care team.[42] An older method of SMBP monitoring involved having the patients measure their BP using a sphygmomanometer with stethoscope and a BP cuff. However, this approach is currently not standard of care and not recommended.[43] Unlike ABPM, where a device is worn consistently during daily activity over a 24-hour period, SMBP monitoring is performed at set times (i.e., morning and evening) while the patient is seated and resting at home or another comfortable place (e.g., while traveling). SMBP devices are well-tolerated and widely available, making SMBP monitoring more appropriate for many patients.[44] Further, there are multiple randomized controlled trials that have shown that SMBP monitoring reduces BP and improves BP control among individuals with hypertension.

SMBP devices are not currently covered under Medicare. Costing on average $60 out-of-pocket, and $732 per year for the device plus supportive care [45] SMBP devices are prohibitively expensive for some patients, especially seniors living on fixed incomes.[46] By removing the cost barrier, coverage of SMBP devices can help to improve hypertension management for lower-income individuals, as well as others with hypertension for whom office BP measurements and ABPM are not the most appropriate options.

Across the health care system, a lack of access to appropriate care and treatment perpetuates health disparities. Poverty is closely linked to heart health; at the county level, it is a stronger predictor of poor

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[40] Whelton PK, Carey RM, Aronow WS, Casey DE, Jr., Collins KJ, Dennison Himmelfarb C, DePalma SM, Gidding S, Jamerson KA, Jones DW, MacLaughlin EJ, Muntner P, Ovbiagele B, Smith SC, Jr., Spencer CC, Stafford RS, Taler SJ, Thomas RJ, Williams KA, Sr., Williamson JD, Wright JT, Jr. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Hypertension. 2018;71:e13-e115.

[41] Shimbo D, Abdalla M, Falzon L, Townsend RR, Muntner P. Role of Ambulatory and Home Blood Pressure Monitoring in Clinical Practice: A Narrative Review. *Ann Intern Med*. 2015;163:691-700.

[42] Uhlig K, Balk EM, Patel K, et al. Self-measured blood pressure monitoring: comparative effectiveness. Comparative Effectiveness Review No. 45. (Prepared by the Tufts Evidence-based Practice Center under Contract No. HHSA 290-2007-10055-I.) AHRQ Publication No. 12-EHC002-EF. Rockville, MD: Agency for Healthcare Research and Quality; 2012.

[43] Muntner P, Shimbo D, Carey RM, Charleston JB, Gaillard T, Misra S, Myers MG, Ogedegbe G, Schwartz JE, Townsend RR, Urbina EM, Viera AJ, White WB, Wright JT, Jr., Council on Clinical Cardiology; and Council on Quality of Care and Outcomes Research obotAHACoHCoCDitYCoCaSNCoCRaI. Measurement of Blood Pressure in Humans: A Scientific Statement From the American Heart Association. *Hypertension*. 2019:HYP0000000000000087.

[44] Ernst ME, Bergus GR. Favorable patient acceptance of ambulatory blood pressure monitoring in a primary care setting in the United States: a cross-sectional survey. BMC Fam Pract. 2003;4:15. Published 2003 Oct 8. doi:10.1186/1471-2296-4-15.

[45] Jacob V, Chattopadhyay SK, Proia KK, et al. Economics of Self-Measured Blood Pressure Monitoring: A Community Guide Systematic Review. *Am J Prev Med*. 2017;53(3):e105-e113. doi:10.1016/j.amepre.2017.03.002.

[46] https://www.ama-assn.org/delivering-care/hypertension/home-monitoring-effort-helps-thousands-get-bp-under-control.

cardiovascular outcomes exceeding even insurance coverage.[47] Such disparities can be attributed to community-level differences, such as access to healthy food.[48] The ability to afford care and insufficient health insurance coverage also pose barriers to access that can perpetuate a variety of health problems, including hypertension.[49] When low-income patients cannot afford to purchase a SMBP device out-of-pocket,[50] they may lose an opportunity to track their BP and achieve control of their hypertension.

Given the devasting consequences of hypertension and how BP control has worsened over recent years, we strongly urge CMS to provide coverage of SMBP devices for treatment and management of hypertension. This NCD request seeks to establish coverage for validated SMBP devices in Medicare in accordance with the indications described below. While considerable evidence also supports the use of SMBP in hypertension *diagnosis*, this request focuses only on treatment and management of patients with hypertension.

In support of this request, we have provided information from recent peer reviewed literature that demonstrates that SMBP is an effective tool for BP management for patients with hypertension, and that adoption of SMBP is currently limited by a lack of coverage. This evidence is summarized below. Further detail on this evidence is available in the accompanying review.[51] Providing access to this important device will help ensure that patients and providers get the clinical information they need to manage Medicare beneficiaries' hypertension.

Benefit category

The proposed benefit would fall under the following benefit category:

- Durable Medical Equipment

Submitted by

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[47] Khansa Ahmad, Edward W. Chen, Umair Nazir, William Cotts, Ambar Andrade, Amal N. Trivedi, Sebhat Erqou, and Wen-Chih Wu, Regional Variation in the Association of Poverty and Heart Failure Mortality in the 3135 Counties of the United States. Journal of the American Heart Association. 2019;8. https://doi.org/10.1161/JAHA.119.012422.

[48] Global Burden of Disease Collaboration. The Burden of Cardiovascular Diseases Among US States, 1990-2016. JAMA Cardiol. 2018;3(5):375-389. doi:10.1001/jamacardio.2018.0385.

[49] Healthy People 2020. Access to Health Services. Office of Disease Prevention and Health Promotion. Accessed July 27, 2020. At: https://www.healthypeople.gov/2020/topics-objectives/topic/Access-to-Health-Services#:~:text=Access percent20to percent20health percent20care percent20impacts,Inadequate percent20or percent20no percent20insurance percent20coverage.

[50] Whelton PK, Carey RM, Aronow WS, Casey DE, Jr., Collins KJ, Dennison Himmelfarb C, DePalma SM, Gidding S, Jamerson KA, Jones DW, MacLaughlin EJ, Muntner P, Ovbiagele B, Smith SC, Jr., Spencer CC, Stafford RS, Taler SJ, Thomas RJ, Williams KA, Sr., Williamson JD, Wright JT, Jr. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Hypertension. 2018;71:e13-e115.

[51] Shimbo D, Artinian NT, Basile JN, et al. Self-Measured Blood Pressure Monitoring at Home: A Joint Policy Statement From the American Heart Association and American Medical Association [published correction appears in Circulation. 2020 Jul 28;142(4):e64]. *Circulation*. 2020;142(4):e42-e63. doi:10.1161/CIR.0000000000000803.

- American Heart Association (AHA)
- American Medical Association (AMA)

Description of Service

There are three Healthcare Common Procedure Coding System (HCPCS) codes related to self-measured blood pressure monitoring:

- A4663: BP cuff only
- A4670: Automatic BP monitor
- A4660: Sphygmomanometer/BP apparatus with cuff and stethoscope

This request is for coverage of A4663 and A4670.

Evidence Supports Medicare Coverage of SMBP

A large body of evidence and clinical guidelines support the use of SMBP monitoring as an effective tool for hypertension treatment and management.[52,53,54,55,56,57,58,59,60,61,62,63,64,65,66] The 2017 Hypertension Clinical Practice Guidelines recommend that SMBP monitoring be used to treat and manage

[52] Whelton PK, Carey RM, Aronow WS, Casey DE, Jr., Collins KJ, Dennison Himmelfarb C, DePalma SM, Gidding S, Jamerson KA, Jones DW, MacLaughlin EJ, Muntner P, Ovbiagele B, Smith SC, Jr., Spencer CC, Stafford RS, Taler SJ, Thomas RJ, Williams KA, Sr., Williamson JD, Wright JT, Jr. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Hypertension. 2018;71:e13-e115.

[53] Muntner P, Shimbo D, Carey RM, Charleston JB, Gaillard T, Misra S, Myers MG, Ogedegbe G, Schwartz JE, Townsend RR, Urbina EM, Viera AJ, White WB, Wright JT, Jr., Council on Clinical Cardiology; and Council on Quality of Care and Outcomes Research obotAHACoHCoCDitYCoCaSNCoCRaI. Measurement of Blood Pressure in Humans: A Scientific Statement From the American Heart Association. *Hypertension*. 2019:HYP0000000000000087.

[54] Carey RM, Calhoun DA, Bakris GL, Brook RD, Daugherty SL, Dennison-Himmelfarb CR, Egan BM, Flack JM, Gidding SS, Judd E, Lackland DT, Laffer CL, Newton-Cheh C, Smith SM, Taler SJ, Textor SC, Turan TN, White WB. Resistant Hypertension: Detection, Evaluation, and Management: A Scientific Statement From the American Heart Association. *Hypertension*. 2018;72:e53-e90.

[55] Siu AL. Screening for high blood pressure in adults: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2015;163:778-86.

[56] Pickering TG, White WB. ASH Position Paper: Home and ambulatory blood pressure monitoring. When and how to use self (home) and ambulatory blood pressure monitoring. *J Clin Hypertens (Greenwich)*. 2008;10:850-5.

[57] Williams B, Mancia G, Spiering W, Agabiti Rosei E, Azizi M, Burnier M, Clement DL, Coca A, de Simone G, Dominiczak A, Kahan T, Mahfoud F, Redon J, Ruilope L, Zanchetti A, Kerins M, Kjeldsen SE, Kreutz R, Laurent S, Lip GYH, McManus R, Narkiewicz K, Ruschitzka F, Schmieder RE, Shlyakhto E, Tsioufis C, Aboyans V, Desormais I. 2018 ESC/ESH Guidelines for the management of arterial hypertension. *Eur Heart J*. 2018;39:3021-3104.

[58] Nerenberg KA, Zarnke KB, Leung AA, Dasgupta K, Butalia S, McBrien K, Harris KC, Nakhla M, Cloutier L, Gelfer M, Lamarre-Cliche M, Milot A, Bolli P, Tremblay G, McLean D, Padwal RS, Tran KC, Grover S, Rabkin SW, Moe GW, Howlett JG, Lindsay P, Hill MD, Sharma M, Field T, Wein TH, Shoamanesh A, Dresser GK, Hamet P, Herman RJ, Burgess E, Gryn SE, Gregoire JC, Lewanczuk R, Poirier L, Campbell TS, Feldman RD, Lavoie KL, Tsuyuki RT, Honos G, Prebtani APH, Kline G, Schiffrin EL, Don-Wauchope A, Tobe SW, Gilbert RE, Leiter LA, Jones C, Woo V, Hegele RA, Selby P, Pipe A, McFarlane PA, Oh P, Gupta M, Bacon SL, Kaczorowski J, Trudeau L, Campbell NRC, Hiremath S, Roerecke M, Arcand J, Ruzicka M, Prasad GVR, Vallee M, Edwards C, Sivapalan P, Penner SB, Fournier A, Benoit G, Feber J, Dionne J, Magee LA, Logan AG, Cote AM, Rey E, Firoz T, Kuyper LM, Gabor JY, Townsend RR, Rabi DM, Daskalopoulou SS. Hypertension Canada's 2018 Guidelines for Diagnosis, Risk Assessment, Prevention, and Treatment of Hypertension in Adults and Children. *Can J Cardiol*. 2018;34:506-525.

[59] Chia YC, Buranakitjaroen P, Chen CH, Divinagracia R, Hoshide S, Park S, Shin J, Siddique S, Sison J, Soenarta AA, Sogunuru GP, Tay JC, Turana Y, Wang JG, Wong L, Zhang Y, Kario K. Current status of home blood pressure monitoring in Asia: Statement from the HOPE Asia Network. *Journal of Clinical Hypertension*. 2017;19:1192-1201.

[60] Chiang CE, Wang TD, Lin TH, Yeh HI, Liu PY, Cheng HM, Chao TH, Chen CH, Shyu KG, Ueng KC, Chen CY, Chu PH, Sung SH, Wang KL, Li YH, Wang KY, Chiang FT, Lai WT, Chen JH, Chen WJ, Yeh SJ, Chen MF, Lin SJ, Lin JL. The 2017 Focused Update of the Guidelines of the Taiwan Society of Cardiology (TSOC) and the Taiwan Hypertension Society (THS) for the Management of Hypertension. *Acta Cardiol Sin*. 2017;33:213-225.

[61] Gabb GM, Mangoni AA, Anderson CS, Cowley D, Dowden JS, Golledge J, Hankey GJ, Howes FS, Leckie L, Perkovic V, Schlaich M, Zwar NA, Medley TL, Arnolda L. Guideline for the diagnosis and management of hypertension in adults - 2016. *Medical Journal of Australia*. 2016;205:85-9.

[62] Sharman JE, Howes FS, Head GA, McGrath BP, Stowasser M, Schlaich M, Glasziou P, Nelson MR. Home blood pressure monitoring: Australian Expert Consensus Statement. *J Hypertens*. 2015;33:1721-8.

[63] Hypertension: Clinical Management of Primary Hypertension in Adults: National Institute for Health Care Excellence. 2011. https://www.nice.org.uk/guidance/cg127 Accessed: March 16, 2019.

hypertension.[67] For patients with limited access to clinical care, SMBP monitoring can provide a crucial link to care. Although ABPM remains the preferred method of out-of-office BP monitoring for diagnosis, SMBP monitoring is an important part of hypertension management and a critical adjunct to the treatment of hypertension in the United States.

CMS greatly improved access to out-of-office BP monitoring by expanding access to ABPM under Medicare for the diagnosis of hypertension. However, a lack of coverage of SMBP devices continues to inhibit access to BP monitoring among those who would benefit from more long-term BP monitoring for hypertension management.[68]

SMBP devices are currently only covered under Medicare for patients with end-stage renal disease. However, several guidelines, scientific statements, and initiatives also support the use of SMBP monitoring as a primary or alternative approach to ABPM for all patients with hypertension. Alongside the Centers for Disease Control and Prevention (CDC) 6|18 Initiative,[69] the Community Guide,[70,71] and the U.S. Department of Health and Human Services Million Hearts® initiative[72]–and in line with the guidelines that AHA released with the American College of Cardiology (ACC), as well as the American Academy of Physician Assistants (AAPA), Association of Black Cardiologists (ABC), American College of Preventive Medicine (ACPM), American Geriatrics Society (AGS), American Pharmacists Association (APhA), American Society of Hypertension (ASH), American Society for Preventive Cardiology (ASPC),

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[64] Shin J, Park JB, Kim KI, Kim JH, Yang DH, Pyun WB, Kim YG, Kim GH, Chae SC. 2013 Korean Society of Hypertension guidelines for the management of hypertension: part I-epidemiology and diagnosis of hypertension. *Clin Hypertens*. 2015;21:1.

[65] Imai Y, Kario K, Shimada K, Kawano Y, Hasebe N, Matsuura H, Tsuchihashi T, Ohkubo T, Kuwajima I, Miyakawa M, Japanese Society of Hypertension Committee for Guidelines for Self-monitoring of Blood Pressure at H. The Japanese Society of Hypertension Guidelines for Self-monitoring of Blood Pressure at Home (Second Edition). *Hypertension Research - Clinical & Experimental*. 2012;35:777-95.

[66] Parati G, Omboni S, Palatini P, Rizzoni D, Bilo G, Valentini M, Rosei EA, Mancia G. Italian society of hypertension guidelines for conventional and automated blood pressure measurement in the office, at home and over 24 hours. *High Blood Pressure & Cardiovascular Prevention*. 2008;15:283-310.

[67] Whelton PK, Carey RM, Aronow WS, Casey DE, Jr., Collins KJ, Dennison Himmelfarb C, DePalma SM, Gidding S, Jamerson KA, Jones DW, MacLaughlin EJ, Muntner P, Ovbiagele B, Smith SC, Jr., Spencer CC, Stafford RS, Taler SJ, Thomas RJ, Williams KA, Sr., Williamson JD, Wright JT, Jr. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Hypertension. 2018;71:e13-e115.

[68] Sarah Woolsey, Brittany Brown, Brenda Ralls, Michael Friedrichs and Barry Stults. Diagnosing Hypertension in Primary Care Clinics According to Current Guidelines. The Journal of the American Board of Family Medicine March 2017, 30 (2) 170-177; DOI: https://doi.org/10.3122/jabfm.2017.02.160111.

[69] 6|18 Initiative. Evidence Summary, Control High Blood Pressure. Centers for Disease Control and Prevention. At: https://www.cdc.gov/sixeighteen/docs/6-18-evidence-summary-blood-pressure.pdf.

[70] The Community Guide. Cardiovascular Disease: Self-Measured Blood Pressure Monitoring Interventions for Improved Blood Pressure Control – When Used Alone. Community Preventive Services Task Force. 2015.

[71] The Community Guide. Cardiovascular Disease: Self-Measured Blood Pressure Monitoring Interventions for Improved Blood Pressure Control – When Combined with Additional Support. Community Preventive Services Task Force. 2015.

[72] Million Hearts. Self-Measured Blood Pressure Monitoring. U.S. Department of Health and Human Services. At: https://millionhearts.hhs.gov/tools-protocols/smbp.html.

National Medical Association (NMA), and Preventive Cardiovascular Nurses Association (PCNA)[73]-the AHA and the AMA recommend the use of SMBP monitoring for the treatment and management of hypertension.

The CDC 6|18 Initiative, Community Guide, and Million Hearts® initiative recognize the valuable contribution that SMBP monitoring can play in hypertension management. The 6|18 initiative has included expanding access to SMBP monitoring as one of its core strategies, noting that these interventions are both effective and cost-effective compared to usual care.[74] The Community Guide found "strong evidence" that SMBP monitoring interventions, when combined with additional support (i.e., patient counseling, education, or web-based support), are effective and cost effective in improving blood pressure outcomes in patients with high blood pressure.[75] Million Hearts® initiative encourages the use of SMBP monitoring as a means to "improve access to care and quality of care for individuals with hypertension while making BP control more convenient and accessible across the population."[76]

Only validated automatic or semi-automatic oscillometric SMBP devices are recommended for clinical use. BP device validation protocols have been published by the American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI)/International Standards Organization (ISO)[77] and the British Hypertension Society (BHS).[78] An older method of SMBP monitoring involved having the patients measure their BP using a sphygmomanometer with stethoscope and a BP cuff. This method is not considered useful or practical for SMBP monitoring because its utility relies upon users listening through a stethoscope for Korotkoff (heartbeat) sounds to determine SBP and DBP measurements, a technique which is difficult for patients to master.[79] Recent hypertension guidelines

[73] Whelton, P. K., Carey, R. M., Aronow, W. S., Casey, D. E., Collins, K. J., Himmelfarb, C. D., ... & MacLaughlin, E. J. (2017). 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Journal of the American College of Cardiology*, 24430.

[74] 6|18 Initiative. Evidence Summary, Control High Blood Pressure. Centers for Disease Control and Prevention. At: https://www.cdc.gov/sixeighteen/docs/6-18-evidence-summary-blood-pressure.pdf.

[75] The Community Guide. Cardiovascular Disease: Self-Measured Blood Pressure Monitoring Interventions for Improved Blood Pressure Control – When Used Alone. Community Preventive Services Task Force. 2015.

[76] Million Hearts. Self-Measured Blood Pressure Monitoring. U.S. Department of Health and Human Services. At: https://millionhearts.hhs.gov/tools-protocols/smbp.html.

[77] Bruce Alpert, Bruce Friedman, Dave Osborn. (2010). AAMI Blood Pressure Device Standard Targets Home Use Issues. *Association for the Advancement of Medical Instrumentation.* Available at: https://www.aami.org/docs/default-source/uploadedfiles/filedownloads/horizons/behindtech-bpstandard.pdf

[78] British and Irish Hypertension Society. Validated BP Monitors for Home Use. Available at: https://bihsoc.org/bp-monitors/for-home-use/

[79] Whelton, P. K., Carey, R. M., Aronow, W. S., Casey, D. E., Collins, K. J., Himmelfarb, C. D., ... & MacLaughlin, E. J. (2017). 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Journal of the American College of Cardiology*, 24430.

and scientific statements do not recommend using this method for SMBP monitoring.[80,81] Accordingly, this request is primarily for automatic SMBP devices along with BP cuffs.

The evidence review submitted with this NCD request outlines the relevant peer-reviewed literature on SMBP monitoring published between 2008 and 2019. Specifically, this review focuses on the most recent evidence regarding the efficacy of SMBP monitoring as a means of lowering BP, its value as a component of team-based care, and the use of SMBP devices for telehealth with remote patient monitoring. The evidence review contains detailed descriptions of relevant studies, their results, and full references for CMS' consideration; the following section briefly summarizes this evidence.

Description of Proposed Use of Service for Identified Medical Conditions in Target Medicare Population and Medical Conditions for Which It Can Be Used

In 2017, the AHA/ACC published guidelines for the prevention, detection, evaluation, and management of high blood pressure in adults. Included in these guidelines were recommended applications for out-of-office BP monitoring, including ABPM and SMBP monitoring, for the management of hypertension. For the purposes of this request, AHA highlights the AHA/ACC guideline that recommends SMBP monitoring for hypertension treatment and management:

> Follow-up and monitoring after initiation of drug therapy for hypertension control should include systematic strategies to help improve BP, **including use of SMBP monitoring**, team-based care, and telehealth strategies [emphasis added]. [82]

Previously, Medicare beneficiaries only had access to ABPM if they had suspected white-coat hypertension.[83] CMS expanded coverage of ABPM in 2019 for not only suspected white-coat hypertension but also suspected masked hypertension, in part, based on a request from AHA and AMA.[84] Adding coverage of SMBP devices can help expand access to a common and often necessary treatment to help patients achieve BP control.

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[80] Muntner P, Shimbo D, Carey RM, Charleston JB, Gaillard T, Misra S, Myers MG, Ogedegbe G, Schwartz JE, Townsend RR, Urbina EM, Viera AJ, White WB, Wright JT, Jr., Council on Clinical Cardiology; and Council on Quality of Care and Outcomes Research obotAHACoHCoCDitYCoCaSNCoCRaI. Measurement of Blood Pressure in Humans: A Scientific Statement From the American Heart Association. *Hypertension*. 2019:HYP0000000000000087.

[81] Imai Y, Kario K, Shimada K, Kawano Y, Hasebe N, Matsuura H, Tsuchihashi T, Ohkubo T, Kuwajima I, Miyakawa M, Japanese Society of Hypertension Committee for Guidelines for Self-monitoring of Blood Pressure at H. The Japanese Society of Hypertension Guidelines for Self-monitoring of Blood Pressure at Home (Second Edition). *Hypertension Research - Clinical & Experimental*. 2012;35:777-95.

[82] Whelton, P. K., Carey, R. M., Aronow, W. S., Casey, D. E., Collins, K. J., Himmelfarb, C. D., ... & MacLaughlin, E. J. (2017). 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Journal of the American College of Cardiology*, 24430.

[83] Centers for Medicare & Medicaid Services. (2003, Jan, 16). Decision Memo for Ambulatory Blood Pressure Monitoring https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=6&NCDId=254&ncdver=2&ver=6&TAId=27&IsPopup=y&bc=AAAAAAAACAAAAA percent3d percent3d&.

[84] TO: Administrative File: CAG-00067R2. FROM: Tamara Syrek Jensen, et al. National Coverage Determination for Ambulatory Blood Pressure Monitoring. Centers for Medicare & Medicaid Services. July 2, 2019. At: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=294.

Indications

Based on the guidelines noted above, we request coverage of SMBP devices for use by patients with diagnosed hypertension to treat and manage hypertension and improve BP control.

Recommendation for a Clinically Beneficial Integration of SMBP into Hypertension Care for the Target Medicare Population

Evidence of Medical Benefit

Numerous studies support SMBP monitoring as an accepted and integral component of care for patients with hypertension. Nearly all providers (96.8 percent) report using SMBP monitoring with some patients, most often for a combination of diagnostic and treatment purposes (59.9 percent) and with clinical supervision (99.5 percent).[85] However, according to patient self-reporting, only 38 percent to 43 percent of U.S. adults with hypertension use SMBP monitoring.[86] This phenomenon suggests that physicians play an important role in counselling patients to use SMBP for BP management. According to another study, approximately 30 percent of patients with hypertension report receiving a physician's recommendation for SMBP (30.1 percent). Of these patients, 82 percent use SMBP, compared to only 28.3 percent of patients who did not receive a physician recommendation.[87]

By making SMBP monitoring more accessible, regular BP measurements over time can reduce BP among older adults,[88] and motivate changes in risky behaviors including cigarette smoking and alcohol consumption.[89] By identifying potential risks before they become severe, SMBP monitoring supports older adults in leading independent lifestyles without relying on caretakers or frequent clinical visits.[90]

For some patients, SMBP monitoring offers a more effective alternative to office measurement or ABPM. Office readings are not always accurate for older adults. In a study of older Japanese adults, SMBP was a more accurate predictor of stroke risk than office BP, suggesting that out-of-office blood

[85] Ostchega Y, Berman L, Hughes JP, Chen TC, Chiappa MM. Home blood pressure monitoring and hypertension status among US adults: the National Health and Nutrition Examination Survey (NHANES), 2009-2010. *Am J Hypertens*. 2013;26:1086-92.

[86] Ostchega Y, Berman L, Hughes JP, Chen TC, Chiappa MM. Home blood pressure monitoring and hypertension status among US adults: the National Health and Nutrition Examination Survey (NHANES), 2009-2010. *Am J Hypertens*. 2013;26:1086-92.

[87] Tang, O., Foti, K., Miller III, E. R., Appel, L. J., Juraschek, S. P. Factors Associated With Physician Recommendation of Home Blood Pressure Monitoring and Blood Pressure in the US Population. American Journal of Hypertension. 2020; 33(9):852–859.

[88] APA Tzourio, Christophe; Hanon, Olivier; Godin, Ophélia; Soumaré, Aicha; Dufouil, Carole Impact of home blood pressure monitoring on blood pressure control in older individuals, Journal of Hypertension: March 2017 - Volume 35 - Issue 3 - p 612-620. doi: 10.1097/HJH.0000000000001191.

[89] Kim JY, Wineinger NE, Steinhubl SR. The Influence of Wireless Self-Monitoring Program on the Relationship Between Patient Activation and Health Behaviors, Medication Adherence, and Blood Pressure Levels in Hypertensive Patients: A Substudy of a Randomized Controlled Trial. *J Med Internet Res*. 2016;18(6):e116. Published 2016 Jun 22. doi:10.2196/jmir.5429.

[90] Nervo Verdezoto and Erik Gro¨nvall. On preventive blood pressure self-monitoring at home. Cogn Tech Work (2016) 18:267–285 DOI 10.1007/s10111-015-0358-7.

pressure monitoring (i.e., ABPM and SMBP monitoring) can play an important role in stroke prevention.[91]

SMBP monitoring as a means of lowering BP

Research demonstrates that SMBP monitoring, compared to usual care without SMBP monitoring, can help lower BP and improve BP control. The use of SMBP monitoring alone without co-interventions (e.g., educational materials or classes, behavioral change management, communicating treatment recommendations to patients, telemonitoring, telecounseling, medication management by nurses or pharmacists, adherence contracts, and prescription monitoring) has been found to reduce SBP and DBP.[92,93] Recent findings have confirmed that the effectiveness of SMBP monitoring is augmented by the presence and types of co-interventions implemented alongside SMBP monitoring.[94,95]

When SMBP monitoring is accompanied by co-interventions, long-term reductions in BP and BP maintenance can be sustained.[96] The benefits of SMBP monitoring may be strongest among patients over age 60.[97] Among older adults, regular SMBP monitoring every three months consistently produced larger reductions in office and home SBP and DBP at 12 and 24 months, compared to annual office and home-based measurement.[98]

Therapeutic inertia, defined as a lack of change in BP medication despite continued uncontrolled BP, is more common among adults over 60 years of age. Compared to office-based BP measurement, SMBP monitoring can reduce therapeutic inertia by promoting medication titration. Among providers using SMBP monitoring for patients with hypertension, 98.5 percent report making medication changes based

[91] Murakami, Keiko, et al. Home blood pressure predicts stroke incidence among older adults with impaired physical function: the Ohasama study. Journal of Hypertension, Volume 35, Number 12, December 2017, pp. 2395-2401(7). https://doi.org/10.1097/HJH.0000000000001473.

[92] Uhlig K, Patel K, Ip S, Kitsios GD, Balk EM. Self-measured blood pressure monitoring in the management of hypertension: a systematic review and meta-analysis. *Ann Intern Med*. 2013;159:185-94.

[93] Reboussin DM, Allen NB, Griswold ME, Guallar E, Hong Y, Lackland DT, Miller EPR, 3rd, Polonsky T, Thompson-Paul AM, Vupputuri S. Systematic Review for the 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2018;71:2176-2198.

[94] Bray EP, Holder R, Mant J, McManus RJ. Does self-monitoring reduce blood pressure? Meta-analysis with meta-regression of randomized controlled trials. *Ann Med*. 2010;42:371-86.

[95] Glynn LG, Murphy AW, Smith SM, Schroeder K, Fahey T. Self-monitoring and other non-pharmacological interventions to improve the management of hypertension in primary care: a systematic review. *British Journal of General Practice*. 2010;60:e476-88.

[96] Tucker KL, Sheppard JP, Stevens R, Bosworth HB, Bove A, Bray EP, Earle K, George J, Godwin M, Green BB, Hebert P, Hobbs FDR, Kantola I, Kerry SM, Leiva A, Magid DJ, Mant J, Margolis KL, McKinstry B, McLaughlin MA, Omboni S, Ogedegbe O, Parati G, Qamar N, Tabaei BP, Varis J, Verberk WJ, Wakefield BJ, McManus RJ. Self-monitoring of blood pressure in hypertension: A systematic review and individual patient data meta-analysis. *PLoS Med*. 2017;14:e1002389.

[97] Aekplakorn W, Suriyawongpaisal P, Tansirisithikul R, Sakulpipat T, Charoensuk P. Effectiveness of Self-Monitoring Blood Pressure in Primary Care: A Randomized Controlled Trial. *J Prim Care Community Health*. 2016;7(2):58-64. doi:10.1177/2150131915614069.

[98] APA Tzourio, Christophe; Hanon, Olivier; Godin, Ophélia; Soumaré, Aicha; Dufouil, Carole Impact of home blood pressure monitoring on blood pressure control in older individuals, Journal of Hypertension: March 2017 - Volume 35 - Issue 3 - p 612-620. doi: 10.1097/HJH.0000000000001191.

on self-measured BP readings.[99] Adjusting medication dosage based on changes in a patient's condition can promote greater BP control, which has been shown to help lower BP.[100] In this way, SMBP monitoring equips providers to improve the quality of care provided and achieve greater health improvements for their patients.

SMBP monitoring as a component of an effective team-based approach to lowering BP

SMBP monitoring provides the needed link between the clinic and the patient's day-to-day life, where self-monitoring is crucial. SMBP readings can provide data on daily fluctuations in a patient's BP, which may help predict future health issues, such as cardiovascular events. Furthermore, by giving patients a more active role in the management of their disease, SMBP monitoring can help improve antihypertensive medication adherence.[101,102]

As discussed above, SMBP monitoring is especially effective when combined with co-interventions, including patient education and training, medication management, and behavioral health counseling, among others. Because SMBP monitoring requires a certain level of knowledge about how to use the device, how to read the measurement, and how to send the readings to the physician or other health professional who is managing the patient's hypertension treatment plan, patients express a desire for more education and regular communication with their clinicians.[103,104] Training resources[105,106] and supportive patient/clinician interactions[107,108] can facilitate patients taking more accurate readings, adhering to the monitoring schedule, and reporting these measurements. Payment for the time and resources required to educate and support patients in using SMBP monitoring, which is already available through CPT codes 99473 and 99474, may be helpful to clinicians offering their time and resources available for SMBP-related activities.[109]

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[99] Jackson SL, Ayala C, Tong X, Wall HK. Clinical Implementation of Self-Measured Blood Pressure Monitoring, 2015-2016. *Am J Prev Med*. 2019;56:e13-e21.

[100] Rajiv Agarwal, Jennifer E. Bills, Tyler J.W. Hecht, and Robert P. Light. Role of Home Blood Pressure Monitoring in Overcoming Therapeutic Inertia and Improving Hypertension Control. Hypertension. 2011;57:29–38.

[101] Bonafini, Sara & Fava, Cristiano. (2015). Home blood pressure measurements: Advantages and disadvantages compared to office and ambulatory monitoring. Blood pressure. 24. 1-8. 10.3109/08037051.2015.1070599.

[102] Tang, O., Foti, K., Miller III, E. R., Appel, L. J., Juraschek, S. P. Factors Associated With Physician Recommendation of Home Blood Pressure Monitoring and Blood Pressure in the US Population. American Journal of Hypertension. 2020; 33(9):852–859.

[103] Grant S, Hodgkinson JA, Milner SL, Martin U, Tompson A, Hobbs FR, Mant J, McManus RJ, Greenfield SM. Patients' and clinicians' views on the optimum schedules for self-monitoring of blood pressure: a qualitative focus group and interview study. *Br J Gen Pract*. 2016;66:e819-e830.

[104] Huff LS, Zittleman L, DeAlleaume L, Bernstein J, Chavez R, Sutte C, LeBlanc WG, Parnes B. What keeps patients from adhering to a home blood pressure program? *J Am Board Fam Med*. 2011;24:370-9.

[105] American Heart Association and American Medical Association. TARGET: BP. https://targetbp.org/tools-downloads/ Accessed: April 10, 2019.

[106] National Association of Community Health Centers. How to Use Your Blood Pressure Monitor. https://www.youtube.com/watch?v=K9HU2F3TOaI&feature=youtu.be Accessed: April 10, 2019.

[107] National Association of Community Health Centers. Self-Measurement: How patients and care teams are bringing blood pressure to control. . https://www.youtube.com/watch?v=XGO-I59UMDg&feature=youtu.be Accessed: April 10, 2019.

[108] Million Hearts. https://millionhearts.hhs.gov/tools-protocols/smbp.html Accessed: April 10, 2019.

[109] Kronish IM, Kent S, Moise N, Shimbo D, Safford MM, Kynerd RE, O'Beirne R, Sullivan A, Muntner P. Barriers to conducting ambulatory and home blood pressure monitoring during hypertension screening in the United States. *J Am Soc Hypertens*. 2017;11:573-580.

To maximize the effectiveness of SMBP monitoring, the Agency for Healthcare Research and Quality (AHRQ) has identified the following additional supports to complement SMBP monitoring:

- One-on-one patient counseling on medication use and health behavior changes;
- Education about high blood pressure and blood pressure self-management; and
- Access to electronic or web-based tools.[110]

More widespread support and reimbursement for SMBP devices alongside new codes to promote telehealth and telemonitoring can help facilitate the adoption of such practices in hypertensive care.[111,112]

SMBP monitoring to promote health equity

SMBP monitoring is critical to narrowing disparities and improving blood pressure control in low-income and medically underserved communities, rural communities and communities of color that experience significant disparities in hypertension rates.[113] Historical racial/ethnic disparities in BP control[114,115] persist today,[116,117] and result in higher rates of hypertension among Black Americans and those of lower socioeconomic status, including in the Medicare program. Hypertension is also more prevalent in rural areas than in urban areas.[118]

Significant barriers to care and treatment can prevent disadvantaged communities from gaining control of their hypertension. Medically underserved communities by definition lack sufficient access to primary

[110] CDC. Self-measured blood pressure control monitoring: action steps for clinicians. Atlanta, GA: CDC, Department of Health and Human Services; 2014.

[111] Lv N, Xiao L, Simmons ML, Rosas LG, Chan A, Entwistle M. Personalized Hypertension Management Using Patient-Generated Health Data Integrated With Electronic Health Records (EMPOWER-H): Six-Month Pre-Post Study. *J Med Internet Res*. 2017;19:e311.

[112] Daichi Shimbo, MD, Chair, Nancy T. Artinian, PhD, RN, FAHA, Jan N. Basile, MD, FAHA, Lawrence R. Krakoff, MD, FAHA, Karen L. Margolis, MD, MPH, Michael K. Rakotz, MD, FAHA, Gregory Wozniak, PhD, On behalf of the American Heart Association and the American Medical Association. Self-Measured Blood Pressure Monitoring at Home: A Joint Policy Statement From the American Heart Association and American Medical Association. *Circulation.* 2020;141. DOI: 10.1161/CIR.0000000000000803.

[113] American Heart Association. American Heart Association and American Medical Association urge broader adoption of self-measured blood pressure monitoring. June 22, 2020. https://newsroom.heart.org/news/american-heart-association-and-american-medical-association-urge-broader-adoption-of-self-measured-blood-pressure-monitoring.

[114] Hertz RP, Unger AN, Cornell JA, Saunders E. Racial disparities in hypertension prevalence, awareness, and management. Arch Intern Med. 2005;165(18):2098-2104. doi:10.1001/archinte.165. 18.2098.

[115] Burt VL, Cutler JA, Higgins M, et al. Trends in the prevalence, awareness, treatment, and control of hypertension in the adult US population: data from the health examination surveys, 1960 to 1991. Hypertension. 1995;26(1):60-69. doi:10.1161/01.HYP. 26.1.60.

[116] Whelton PK. The elusiveness of population-wide high blood pressure control. Annu Rev Public Health.2015;36:109-130. doi:10.1146/annurev-publhealth-031914-122949.

[117] Muntner P, Carey RM, Gidding S, et al. Potential US population impact of the 2017 ACC/AHA highblood pressure guideline. J AmColl Cardiol. 2018;71(2):109-118. doi:10.1016/j.jacc.2017.10.073.

[118] Centers for Medicare and Medicaid Services. Rural-Urban Disparities in Health Care in Medicare. November 2019. At: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Urban-Disparities-in-Health-Care-in-Medicare-Report.pdf.

medical care.[119] There are thousands of medically underserved areas across the United States,[120] where population to provider ratios can exceed multiple thousands to one.[121] Patients in these areas may find it difficult or impossible to regularly visit their provider due to long travel times and limited appointment availability. For patients without easy access to treatment and monitoring, SMBP monitoring may be necessary to help them achieve BP control.

By enabling patients and providers to monitor BP at home, SMBP monitoring can help fill in the gaps in care that contribute to disparities in BP control. In a pilot study, researchers were able to facilitate BP control among 80 percent of patients with uncontrolled hypertension within six months after the intervention by providing them with a free SMBP device, online and print resources for tracking their readings, and monitoring reminders. At the end of the intervention, systolic blood pressures had decreased an average 16.9 mmHg and diastolic blood pressures fell an average 6.5 mmHg.[122] These finding suggest that greater access to SMBP devices among underserved communities, rural communities, and communities of color could significantly improve disparities in hypertension and BP control.

SMBP monitoring to facilitate telehealth

Telehealth counseling, as a co-intervention, is recommended in conjunction with SMBP monitoring.[123] The ability to communicate with patients remotely serves a variety of purposes. Primarily, it enables providers to not only speak with but also monitor patients outside of the clinical setting, which can be especially useful for patients with limited mobility or physical access to their provider, such as in rural areas. During the COVID-19 pandemic, CMS is waiving the requirement to see patients in-office in order to bill for services and use of telehealth services has increased substantially.[124,125] This coverage has been essential as the novel coronavirus presents significant barriers to in-office BP monitoring, especially to seniors and others who are vulnerable to a more severe adverse impact from the virus. ABPM, too, requires office visits to place the device and, later, to return it. SMBP education via

[119] HRSA. Medically Underserved Areas and Populations (MUA/Ps). May 2020. At: https://bhw.hrsa.gov/shortage-designation/muap.

[120] HRSA. MUA Find [database]. At: https://data.hrsa.gov/tools/shortage-area/mua-find.

[121] County Health Rankings. Primary Care Physicians: Explore the Data. 2020. At: https://www.countyhealthrankings.org/explore-health-rankings/measures-data-sources/county-health-rankings-model/health-factors/clinical-care/access-to-care/primary-care-physicians.

[122] American Heart Association. Monitoring at home yields better blood pressure control American Heart Association Meeting Report - Presentation P351. Newsroom. 2018. At: https://newsroom.heart.org/news/monitoring-at-home-yields-better-blood-pressure-control.

[123] Whelton PK, Carey RM, Aronow WS, Casey DE, Jr., Collins KJ, Dennison Himmelfarb C, DePalma SM, Gidding S, Jamerson KA, Jones DW, MacLaughlin EJ, Muntner P, Ovbiagele B, Smith SC, Jr., Spencer CC, Stafford RS, Taler SJ, Thomas RJ, Williams KA, Sr., Williamson JD, Wright JT, Jr. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Hypertension. 2018;71:e13-e115.

[124] The American Medical Association. How to code for SMBP? AMA guides break down CPT during pandemic. May 28, 2020. At: https://tele.healthcare/how-to-code-for-smbp-ama-guides-break-down-cpt-during-pandemic/.

[125] Rebecca Pifer. Medicare members using telehealth grew 120 times in early weeks of COVID-19 as regulations eased. Health Care Dive. May 27, 2020. https://www.healthcaredive.com/news/medicare-seniors-telehealth-covid-coronavirus-cms-trump/578685/.

telehealth and SMBP monitoring along with telehealth visits is a reasonable solution to help fill in these gaps and maintain continuity of care for patients with hypertension through the pandemic. However, while barriers to telehealth were lifted, barriers to accessing an SMBP device remain for many patients. Patients report that the out-of-pocket costs of SMBP devices deter them from utilizing this form of otherwise beneficial care.[126]

The COVID-19 pandemic has accelerated a trend already underway in hypertension care. By extending coverage of ABPM in Medicare, CMS facilitated the expansion of chronic disease care beyond the clinic. Telehealth further enables providers to interact with their patients at home, which can improve outcomes among chronic disease patients.[127,128] As the "new normal" settles in, and patients who live far from a clinic or have limited mobility establish routine BP measurement and telehealth check-ins, coverage of SMBP devices will help facilitate continuity of care and support BP control.[129] Further, unlike ABPM devices, which belong to and must be returned to medical offices after the 24-hour measurement period, patients own their SMBP devices, and can use and reuse them over short, long, and intermittent periods of time according to their needs. Along with telehealth, SMBP monitoring offers patients effective and more flexible ongoing support to manage their condition without the physical need to come into the office for an in-office measurement of BP.

Coverage of SMBP devices Will Help Improve Medical Benefit to the Target Population

The evidence outlined in this document and the supporting evidence review reinforce the case for SMBP monitoring as an effective tool to improve the management and treatment of hypertension leading to improved BP control, yet Medicare does not cover SMBP devices. The establishment of coverage for SMBP devices is reasonable and necessary, and would considerably benefit Medicare beneficiaries, particularly those in low-income, rural, or racial minority communities who are disproportionately impacted by hypertension. Alongside complementary supportive services, such as telehealth, SMBP monitoring is effective at enabling patients to track their BP and allowing clinicians to titrate medications and provide education, which can help ensure Medicare beneficiaries receive appropriate treatment tailored to their individual health needs. SMBP monitoring is well suited to help manage disease, as hypertension is associated with a number of negative health outcomes, and BP control is associated with reduced risk of these outcomes. Finally, by facilitating telehealth, SMBP monitoring addresses health equity concerns among underserved populations who may face additional barriers to accessing care and treatment in a clinical setting.

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[126] Carter EJ, Moise N, Alcantara C, Sullivan AM, Kronish IM. Patient Barriers and Facilitators to Ambulatory and Home Blood Pressure Monitoring: A Qualitative Study. *Am J Hypertens*. 2018;31:919-27.

[127] Laurence C. Baker, Scott J. Johnson, Dendy Macaulay, and Howard Birnbaum. Integrated Telehealth And Care Management Program For Medicare Beneficiaries With Chronic Disease Linked To Savings. Health Affairs. 2011; 30(9). https://doi.org/10.1377/hlthaff.2011.0216.

[128] Lu, J.-F., Chen, C.-M., & Hsu, C.-Y. (2019). Effect of home telehealth care on blood pressure control: A public healthcare centre model. Journal of Telemedicine and Telecare, 25(1), 35–45. https://doi.org/10.1177/1357633X17734258.

[129] Mehrotra A, Jena AB, Busch AB, Souza J, Uscher-Pines L, Landon BE. Utilization of Telemedicine Among Rural Medicare Beneficiaries. JAMA. 2016;315(18):2015–2016. doi:10.1001/jama.2016.2186.