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September 16, 2021

Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Request for National Coverage Determination for Self-Measured Blood Pressure (SMBP)
Monitoring Devices

Dear Director Jensen:

On behalf of the American Heart Association (AHA) and the American Medical Association (AMA), we are submitting a formal request for a National Coverage Determination (NCD) for validated self-measured blood pressure (SMBP) monitoring devices for the diagnosis and management of hypertension for Medicare beneficiaries. This letter is a follow-up to our October 23, 2020,¹ request and outlines a suggested operational structure for how SMBP monitoring device coverage can be linked to the existing, previously approved Medicare covered clinical services for SMBP monitoring.² Blood pressure (BP) readings using validated devices, and in conjunction with clinical support (e.g., one-on-one counseling, web-based or telephonic support tools, education), can be used to more accurately diagnose and effectively manage hypertension than in-office readings alone.

BP control rates heading in the wrong direction; disparities in outcomes widening

After a steady increase of US adults with controlled blood pressure, the numbers are now heading in the wrong direction, with an estimated 60 percent of those with hypertension not in control. An analysis of National Health and Nutrition Examination Survey (NHANES) data found that adults with controlled blood pressure increased from 31.8 percent in 1999-2000 to 48.5 percent in 2007-2008. This rate remained stable and then declined to 43.7 percent from 2017-2018.³ In addition, ethnic and racial differences in BP control continue among US adults, with a lower proportion of non-Hispanic Black adults having controlled BP compared with non-Hispanic White adults, for example.^{4,5}

One of the likely consequences of the disruption of in-person primary care visits during the pandemic is that we have begun to see signs that control rates for adults with hypertension have further deteriorated. While a 30-fold increased use of telehealth services occurred in primary care early in the pandemic, most patients do not have access to validated SMBP monitoring devices at home. This almost certainly was a contributing factor to BP being assessed at less than 10% of telemedicine visits.⁶ Without access to SMBP monitoring devices, patients cannot measure and share SMBP readings with their physicians to support accurate diagnosis and treatment of hypertension.

The best available science supports the use of SMBP monitoring for improved diagnosis and management of hypertension

For many people, BP measured outside of the office differs greatly from BP measured inside the office. SMBP monitoring is a well-validated approach of measuring BP outside of the office. SMBP is a more accurate predictor of cardiovascular events and mortality than office-measured blood pressure. Current US guidelines, scientific statements, and the 2020 US Surgeon General's Call to Action recommend the use of out-of-office BP measurements for confirming a diagnosis of hypertension, titrating treatment, and following up to assess BP control.⁷ For diagnosing hypertension, the 2017 Hypertension Clinical Practice Guideline stated that it is reasonable to use SMBP monitoring to identify white coat hypertension and masked hypertension among adults with and without high office BP, respectively.⁸ The United States Preventive Services Task Force Hypertension in Adults: Screening recommendation calls for obtaining blood pressure measurements outside of the clinical setting for diagnostic confirmation before starting treatment.⁹

SMBP monitoring is also useful for improving BP control among patients who have been diagnosed with hypertension. Several meta-analyses of randomized controlled trials indicate that the use of SMBP monitoring leads to reductions in BP and improved BP control among individuals with hypertension. **Overall, there is strong and compelling evidence to indicate that SMBP monitoring provides benefit to managing hypertension.** For adults over age 60, treating hypertension to achieve blood pressure control is associated with reduced stroke and adverse cardiac events. In addition, this adult population is often taking additional medication. Physicians need to weigh possible medication interactions and/or any potential burden of additional treatment before prescribing hypertensive medication or intensifying treatment. SMBP services with a BP monitoring device can provide this needed clinical information.¹⁰

Organized medicine and federal government support for SMBP monitoring

The American College of Cardiology and American Heart Association clinical practice guidelines for the prevention, detection, evaluation, and treatment of high blood pressure in adults state that although ambulatory BP monitoring (ABPM) is generally accepted as the best out-of-office measurement method for diagnosing hypertension, SMBP monitoring is a more practical approach in clinical practice for diagnosing and assessing BP control over time to manage hypertension.⁸ National medical specialty and other professional societies including the American Academy of Family Physicians, American Academy of Physician Assistants, American College of Physicians, American College of Preventive Medicine, American Geriatrics Society, American Pharmacists Association, American Society of Hypertension, American Society for Preventive Cardiology, Association of Black Cardiologists, National Medical

Association, and Preventive Cardiovascular Nurses Association, all support the use of SMBP monitoring for the diagnosis and management of hypertension.

SMBP monitoring is also supported by programmatic initiatives of several federal agencies. For example, the Department of Health and Human Services’ “Million Hearts” initiative, co-led by the Centers for Disease Control and Prevention (CDC) and Centers for Medicare & Medicaid Services (CMS), identified SMBP monitoring as a best practice strategy to reach its goal of achieving blood pressure control in individuals with uncontrolled hypertension. CDC’s Community Preventive Services Task Force strongly recommends the use of SMBP with clinical support for hypertension management. SMBP monitoring is listed as one of 8 best practice strategies in the CDC Community Best Practices Guide for CVD Prevention. The 2020 US Surgeon General’s Call to Action to Control Hypertension recommends that patients should be actively engaged by their clinical team in managing their BP and be provided with a validated home BP monitor with an appropriate cuff size. In addition, in 2021, through the National Hypertension Control Initiative, the Health Resources and Services Administration (HRSA) and Office of Minority Health are partnering to improve hypertension control, including providing patients with hypertension a connected SMBP monitoring device at HRSA-funded health centers.¹¹

Current status of coverage for SMBP monitoring

Based on the strength of the evidence, the 2020 Medicare Physician Fee Schedule added CPT® codes 99473 and 99474 to enable effective SMBP monitoring, including patient training to use a SMBP monitoring device validated for clinical accuracy and ongoing clinical support. However, a major gap currently exists in ensuring the successful delivery of SMBP monitoring: the validated devices themselves, which are required for reimbursement of SMBP monitoring, are not covered. The requirement to purchase SMBP monitoring devices and associated out-of-pocket costs has been raised as a concern by both patients and physicians, and therefore, the lack of SMBP monitoring device coverage remains a barrier to the successful implementation of SMBP. The lack of device coverage does not allow physicians to provide the same level of care for all patients since it is dependent on patients purchasing the devices out-of-pocket. Providing coverage for validated SMBP monitoring devices would directly address this clinical gap in providing SMBP monitoring services (i.e., lack of coverage for the monitoring devices) for the diagnosis and management of hypertension, thus addressing known health inequities.

Proven return on investment for SMBP

In 2020, the American Heart Association and AMA published a Policy Statement on SMBP Monitoring at Home, finding that self-measured BP monitoring used with a team-based approach is cost-effective.¹² In addition, providing a SMBP monitoring device to patients is associated with a positive return on investment for insurers when the three uses of SMBP are employed together with clinical oversight: for diagnosis, for medication selection and titration, and for monitoring blood pressure regularly.¹³

Excerpt from Table 1. Financial impact of SMBP (ROI, NPV) from the perspective of a private insurer.

	1-Year ROI	1-Year NPV	Lifetime NPV
Age 65-75	79%	\$50	\$56

Age 75-84	36%	\$22	\$16
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SMBP monitoring devices meet the statutorily defined benefit category for durable medical equipment (DME), covered under Medicare Part B

SMBP devices meet all four requirements outlined by CMS for DME:

- Can withstand repeated use
- Primarily and customarily used to serve a medical purpose
- Useful to a person with a diagnosed medical condition
- Appropriate for use in the home

Item/Service Description

Non-invasive blood pressure devices are FDA 510(k) cleared Class II medical devices. The SMBP monitoring devices used by patients to collect blood pressure readings outside of the clinical office can range from mechanical aneroid gauges (sphygmomanometers) that require self-inflation and self-auscultation to those that automatically inflate the cuff (placed on the upper arm or wrist as designed) and display the reading. Use of auscultatory devices (mercury, aneroid, or other) is not generally useful for SMBP because patients rarely master the technique required for measurement of BP with auscultatory devices. Automated devices validated for clinical accuracy are more appropriate for accurate measurement of BP outside of the clinical setting. Validated SMBP monitoring devices have met internationally accepted validation testing protocols to ensure accurate readings appropriate for clinical decision making. Validated, oscillometric, upper arm devices that can store readings in memory are recommended in the 2019 Measurement of Blood Pressure in Humans a Scientific Statement from the American Heart Association.

Applicable HCPCS code(s):

A4670: Automated blood pressure monitor

A4663: Blood pressure cuff only

Indications and Limitations of Coverage

Based on the guidelines noted above, we request coverage of validated SMBP monitoring devices for use to confirm a diagnosis of hypertension and to manage hypertension to improve BP control. Like home blood glucose monitors, SMBP monitoring devices enable individuals to partner with their clinical care team to better manage and control their condition by frequently assessing it and appropriately sharing their data with their physician for advice about treatment. Coverage of SMBP monitoring devices would be limited to patients meeting the following conditions:

- The patient has been diagnosed with hypertension, OR
- The patient is suspected of having hypertension, or the physician is ruling out white coat or masked hypertension; AND

- By prescribing SMBP monitoring, the patient’s physician states that the patient is capable of being trained to use the validated device prescribed in an appropriate manner. In some cases, the patient may not be able to perform this function, but a responsible individual can be trained to use the equipment and the clinical team can monitor the patient to assure that the intended use is achieved. This approach is permissible if the record is properly documented by the patient’s physician.

Suggested limitations:

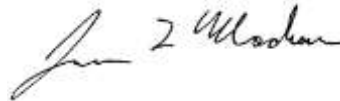
- The SMBP monitoring devices covered should be validated for clinical accuracy and designated for use in the home. The **US Blood Pressure Validated Device Listing (VDL™)** is the first list of validated BP measurement devices for the United States; the list was developed to assist physicians and patients in identifying those devices that have been validated for clinical accuracy.
- Patients should be trained on the proper use and positioning of the device, as well as how to record their readings and submit to their physician for review (related to CPT 99473).

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.

Sincerely,



Nancy Brown
Chief Executive Office
American Heart Association



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

¹ Brown CA, Madara JL. Formal request for an NCD consideration. <https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2020-10-23-Joint-AMA-AHA-Memo-Formal-Request-for-SMBP-NCD.pdf> (accessed August 2, 2021)

² American Medical Association. SMBP CPT® Coding. <https://www.ama-assn.org/system/files/2020-06/smbp-cpt-coding.pdf> (accessed August 2, 2021)

³ Muntner P, Hardy ST, Fine LJ, et al. Trends in Blood Pressure Control Among US Adults With Hypertension, 1999-2000 to 2017-2018. *JAMA*. 2020;324(12):1190–1200. doi:10.1001/jama.2020.14545

⁴ Whelton PK. The elusiveness of population-wide high blood pressure control. *Annu Rev Public Health*. 2015;36:109-130. doi:10.1146/annurev-publhealth031914-122949 1

⁵ Muntner P, Carey RM, Gidding S, et al. Potential US population impact of the 2017 ACC/AHA high blood pressure guideline. *J Am Coll Cardiol*. 2018;71 (2):109-118. doi:10.1016/j.jacc.2017.10.073

⁶ Alexander GC, Tajanlangit M, Heyward J, Mansour O, Qato DM, Stafford RS. Use and Content of Primary Care Office-Based vs Telemedicine Care Visits During the COVID-19 Pandemic in the US. *JAMA Netw Open*. 2020;3(10):e2021476. Published 2020 Oct 1. doi:10.1001/jamanetworkopen.2020.21476

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- ⁷ The Surgeon General’s Call to Action for Hypertension. <https://www.cdc.gov/bloodpressure/docs/SG-CTA-HTN-Control-Report-508.pdf> (accessed September 1, 2021)
- ⁸ Whelton PK, Carey RM, Aronow WS, Casey DE. 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(6):Pages e13-e115
<https://doi.org/10.1161/HYP.0000000000000065>
- ⁹ United States Preventative Services Task Force. Hypertension in Adults: Screening. <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/hypertension-in-adults-screening> (accessed August 3, 2021)
- ¹⁰ American Academy of Family Physicians, American College of Physicians. Pharmacologic treatment of hypertension: ACP and AAFP release recommendations for adults 60 years and older. <https://www.aafp.org/afp/2017/0501/afp20170501p588.pdf> (accessed August 19, 2021)
- ¹¹ Health Services Research Administration. FY 2021 Supplemental Funding for Hypertension (NHCI-HC). <https://bphc.hrsa.gov/program-opportunities/national-hypertension-control-initiative> (accessed September 1, 2021)
- ¹² Shimbo D, Artinian N, Basile J, Krakoff L, Margolis K, Rakotz M, Wozniak G. Self-measured blood pressure monitoring at home: A joint policy statement from the American Heart Association and American Medical Association. <https://doi.org/10.1161/CIR.0000000000000803> *Circulation*. 2020;142:e42–e63
- ¹³ Arrieta A, Woods J, Wozniak G, Tsipas S, Rakotz M, Jay S (2021) Return on investment of self-measured blood pressure is associated with its use in preventing false diagnoses, not monitoring hypertension. *PLoS ONE*(2021);16(6): e0252701.