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May 9, 2019

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

Re: CAG-00067R2 Proposed National Coverage Determination for Ambulatory Blood Pressure Monitoring

Dear Ms. Syrek Jensen:

On behalf of the American Heart Association and the American Medical Association, we would like to thank the Centers for Medicare and Medicaid Services (CMS) for responding to our request for a reconsideration of the Ambulatory Blood Pressure Monitoring (ABPM) National Coverage Determination (NCD) by proposing to expand coverage and issuing a revised coverage determination.

We are pleased that CMS has proposed expanding the covered indications for ABPM to include masked hypertension, as well as making Medicare's ABPM coverage policy consistent with recent changes to the thresholds used for diagnosing hypertension. There are several areas, however, where we believe modifications and corrections are necessary to ensure coverage and use of ABPM that is consistent with published clinical guidelines. Recognizing that office based blood pressure determinations lack the precision needed and reproducibility over multiple office measurements to make an accurate diagnosis of hypertension, it is imperative that the NCD be structured such that it supports the use of ABPM to achieve its fullest potential to reduce the harms caused by hypertension among Medicare beneficiaries as described and given an 'A' rating by the U.S. Preventive Services Task Force (USPSTF)¹.

Specifically, we recommend that CMS:

- Revise the clinical circumstances in which ABPM is appropriate and necessary to be consistent with prior guidelines including the 2017 American Heart Association/American College of Cardiology Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults (referred to as "2017 AHA/ACC guideline"²).

¹ Siu, A. on behalf of U.S. Preventive Services Task Force. Screening for high blood pressure in adults: U.S. Preventive Services Task Force Recommendation Statement. *Ann intern Med.* 2015 Nov; 163(10). doi: 10.7326/M15-223.

² Whelton PK, Carey RM, Aronow WS, Casey Jr. DE, Collins KJ, Himmelfarb CD, DePalma SM, Gidding S, Jamerson KA, Jones DW, MacLaughlin EJ, Muntner P, Ovbiergele B, Smith Jr. SC, Spencer CC, Stafford RS, Taler SJ, Thomas RJ, Williams Sr. KA, Williamson JD and Wright Jr. JT. 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:e127-e248.

- Specify nocturnal hypertension as an indication for ABPM. Nocturnal hypertension can only be diagnosed precisely by ABPM and is common in morbid conditions such as chronic kidney disease, diabetes mellitus, systolic hypertension in older persons, and neurodegenerative diseases.
- Recommend a specific blood pressure device validation protocol rather than referring to a specific website that summarizes whether a device has undergone validation testing.
- Request clarification from CMS regarding the “management” aspect of this proposed coverage determination, given the organizations’ request focused on diagnosis.

We expand upon these recommendations below.

Revise Circumstances Language for Consistency with Clinical Guidelines

In the proposed coverage determination, CMS describes the two circumstances in which it has determined ambulatory blood pressure monitoring is reasonable and necessary, as follows:

1. For beneficiaries with suspected white coat hypertension, which is defined as office blood pressure $\geq 130/80$ mm Hg and $< 160/100$ mm Hg on at least two separate clinic/office visits with two separate measurements made at each visit after 3 months of behavioral interventions including diet and exercise modification and with at least two blood pressure measurements taken outside the office which are $< 130/80$ mm Hg;
2. For beneficiaries with suspected masked hypertension, which is defined as office blood pressure between 120 and 130/80 mm Hg on at least two separate clinic/office visits with two separate measurements made at each visit after 3 months of behavioral interventions including diet and exercise modification and at least two blood pressure measurements taken outside the office which are $\geq 130/80$ mm Hg.

We recommend that the following revisions be made to these conditions to ensure their consistency with previously published definitions and blood pressure thresholds.

First, in both circumstances as proposed in the coverage determination, “3 months of behavioral interventions including diet and exercise modification” would be required before beneficiaries are eligible for ABPM. Lifestyle interventions, as described in the proposed coverage determination, are not an essential criterion since there is no empiric evidence to support first proceeding with lifestyle change before obtaining an immediate diagnosis, confirmation, or exclusion of white coat or masked hypertension. For example, the USPSTF has not required that lifestyle change be conducted first before a diagnosis of hypertension be made using office blood pressure and out-of-office blood pressure. Therefore, we recommend strongly that this portion of the condition be removed.

Second, according to the 2017 AHA/ACC guideline, “an average of ≥ 2 readings obtained on ≥ 2 occasions [be used] to estimate the individual’s level of office blood pressure.” Accordingly, we recommend that the language be revised to indicate an average office blood pressure, not simply two separate office blood pressure readings. Averaging multiple readings is important because it provides a more stable estimate of blood pressure than using one reading.

Third, we request that references to out-of-office measurements before a patient is eligible for coverage of ABPM be removed. As currently written, the phrasing (“blood pressure measurements taken outside the office”) suggests that home blood pressure monitoring be done first before ABPM should be done. The USPSTF-recommended method for diagnosing hypertension is to use ABPM as the out-of-office blood pressure measurement, and when not available, the next recommendation is home blood pressure monitoring as the alternative approach that “may be acceptable.” Home blood pressure monitoring is not currently covered or reimbursed for Medicare patients, and so we are concerned that including this step not only does not align with the USPSTF recommendations or clinical guidelines, but will also confuse

practitioners and deter use of ABPM since there is no coverage for delivering the necessitated previous step. Additionally, it is not clear how patients would obtain a monitor in these circumstances, suggesting that the burden would be on the patient to purchase a monitor, in the absence of coverage. Therefore, we recommend that this requirement be removed.

Lastly, the masked hypertension circumstance appears to be missing a diastolic blood pressure range and the systolic range is incorrect. According to the 2017 ACC/AHA guideline, the threshold should be “between 120 mm Hg and 129 mm Hg for systolic blood pressure or between 75 mm Hg and 79 mm Hg for diastolic blood pressure.”

Based on these recommendations, we propose the revised circumstances read as follows:

1. For beneficiaries with suspected white coat hypertension, which is defined as an average office blood pressure of SBP greater than 130 mm Hg but less than 160 mm Hg or DBP greater than 80 mm Hg but less than 100 mm Hg on two separate clinic/office visits with at least two separate measurements made at each visit.
2. For beneficiaries with suspected masked hypertension, which is defined as average office blood pressure between 120 mm Hg and 129 mm Hg for SBP or between 75 mm Hg and 79 mm Hg for DBP on at two separate clinic/office visits with at least two separate measurements made at each visit.

Specify/Confirm Inclusion of Nocturnal Hypertension Indication

Using previously published nighttime blood pressure thresholds (nighttime systolic blood pressure ≥ 120 mmHg or nighttime diastolic blood pressure ≥ 70 mmHg,^{3,4}) the prevalence of nocturnal hypertension is estimated to be 20-60%⁵ with a very high prevalence being reported among African Americans.⁶ Nocturnal hypertension is defined by the 2017 AHA/ACC 2017 guideline to be a nighttime systolic blood pressure ≥ 110 mmHg or nighttime diastolic blood pressure ≥ 65 mmHg. The prevalence of nocturnal hypertension is likely to be higher using these lower nighttime blood pressure thresholds. Data described in several studies suggest that nighttime blood pressure is a stronger predictor of outcomes compared with daytime blood pressure.^{7,8}^{9,10} Guidelines, including those of the European Society of Hypertension and European Society of

³ Parati G, Stergiou G, O'Brien E, Asmar R, Beilin L, Bilo G, Clement D, de la Sierra A, de Leeuw P, Dolan E, Fagard R, Graves J, Head GA, Imai Y, Kario K, Lurbe E, Mallion JM, Mancia G, Mengden T, Myers M, Ogedegbe G, Ohkubo T, Omboni S, Palatini P, Redon J, Ruilope LM, Shennan A, Staessen JA, vanMontfrans G, Verdecchia P, Waeber B, Wang J, Zanchetti A, Zhang Y; European Society of Hypertension Working Group on Blood Pressure Monitoring and Cardiovascular Variability. European Society of Hypertension practice guidelines for ambulatory blood pressure monitoring. *J Hypertens*. 2014 Jul;32(7):1359-66. doi: 10.1097/HJH.0000000000000221.

⁴ O'Brien E1, Parati G, Stergiou G, Asmar R, Beilin L, Bilo G, Clement D, de la Sierra A, de Leeuw P, Dolan E, Fagard R, Graves J, Head GA, Imai Y, Kario K, Lurbe E, Mallion JM, Mancia G, Mengden T, Myers M, Ogedegbe G, Ohkubo T, Omboni S, Palatini P, Redon J, Ruilope LM, Shennan A, Staessen JA, vanMontfrans G, Verdecchia P, Waeber B, Wang J, Zanchetti A, Zhang Y; European Society of Hypertension Working Group on Blood Pressure Monitoring. European Society of Hypertension position paper on ambulatory blood pressure monitoring. *J Hypertens*. 2013 Sep;31(9):1731-68. doi: 10.1097/HJH.0b013e328363e964.

⁵ Bromfield SG1, Booth JN 3rd2, Loop MS3, Schwartz JE4,5, Seals SR6, Thomas SJ7, Min Y18, Ogedegbe G9, Shimbo D4, Muntner P2. Evaluating different criteria for defining a complete ambulatory blood pressure monitoring recording: data from the Jackson Heart Study. *Blood Press Monit*. 2018 Apr;23(2):103-111. doi: 10.1097/MBP.0000000000000309.

⁶ Booth JN, Anstey DE, Bello NA, Jaeger BC, Pugliese DN, Thomas SJ, Deng L, Shikany JM, Lloyd-Jones D, Schwartz JE, Lewis CE, Shimbo D, Muntner P. Race and sex differences in asleep blood pressure: The Coronary Artery Risk Development in Young Adults (CARDIA) study. *J Clin Hypertens (Greenwich)*. 2019 Feb;21(2):184-192. doi: 10.1111/jch.13474. Epub 2019 Feb 5.

⁷ Boggia J, Li Y, Thijs L, et al. Prognostic accuracy of day versus night ambulatory blood pressure: a cohort study. *Lancet*. 2007;370 (9594):1219-1229.

⁸ ABC-H Investigators, Roush GC, Fagard RH, Salles GF, et al. Prognostic impact from clinic, daytime, and night-time systolic blood pressure in nine cohorts of 13,844 patients with hypertension. *J Hypertens*. 2014;32 (12):2332-2340.

⁹ Sega R, Facchetti R, Bombelli M, et al. Prognostic value of ambulatory and home blood pressures compared with office blood pressure in the general population: follow-up results from the Pressioni Arteriose Monitorate e Loro Associazioni (PAMELA) study. *Circulation*. 2005;111 (14):1777-1783

¹⁰ Staessen JA, Thijs L, Fagard R, et al. Predicting cardiovascular risk using conventional vs ambulatory blood pressure in older patients with systolic hypertension. Systolic Hypertension in Europe Trial Investigators. *JAMA*. 1999;282 (6):539-546.

Cardiology consider the definition of masked hypertension be based not only on daytime blood pressure but also nighttime blood pressure. The proposed definition of masked hypertension, however, would not specifically identify nocturnal hypertension and so we are recommending that an indication be added to enable the use of ABPM to detect cases of suspected nocturnal hypertension.

Validation Protocol

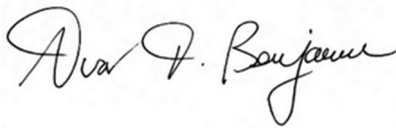
In the proposed coverage determination, CMS proposes a list of requirements for ABPM devices, including that they be “quality-certified and validated for use in the intended patient population by the dabl Educational Trust Ltd. or by a similar blood pressure monitoring device quality control organization.” While we recognize CMS provides leeway for other organizations that reference blood pressure devices that meet quality requirements, we believe that rather than specifying a particular website (whose accuracy cannot be confirmed or lifespan of webhosting is not reported), CMS should specify which validation protocol, such as those developed by the International Organization for Standardization (ISO) and the Association for the Advancement of Medical Instrumentation (AAMI), should be used.

Interaction with Other Services, Management of Hypertension

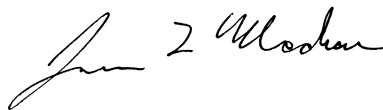
Our initial coverage determination request focused on the use of ABPM for diagnosis of hypertension to match the USPSTF guidance and A rating for “obtaining measurements outside of the clinical setting for diagnostic confirmation before starting treatment.” The proposed coverage determination allows for ABPM for diagnosis “and management.” We were pleased to see that CMS recognizes the role for ABPM in the management of hypertension, but our organizations would also appreciate if CMS could provide some additional clarification about the “management” aspect of this Medicare coverage policy.

In closing, we reiterate the American Heart Association and the American Medical Association appreciation of CMS’s proposed expansion of its National Coverage Determination and encourage CMS to incorporate our proposed revisions. If you or your staff have any questions or would like to discuss our comments further, please do not hesitate to contact Madeleine Konig at madeleine.konig@heart.org or 202-785-7930.

Sincerely,



Ivor J. Benjamin, MD, FAHA
President
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James L. Madara, MD
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