



November 8, 2018

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

Re: National Coverage Analysis on Ambulatory Blood Pressure Monitoring

Submitted at <https://www.cms.gov/medicare-coverage-database/details/submit-public-comment>

Dear Ms. Syrek-Jensen:

The Personal Connected Health Alliance (PCHAlliance), a non-profit membership association, appreciates the opportunity to provide information to support CMS review, analysis and update of its National Coverage Decision (NCD) on Ambulatory Blood Pressure Monitoring, last revised in 2003. Our comments focus on the importance of updating Medicare coverage policy to flexibly reflect evidence-based innovation that delivers improved patient centered health care. We believe that Medicare's coverage policy on measuring and screening for blood pressure to identify cardiovascular risks can be updated to reflect current standard of care in a technology neutral manner.

Interoperable, connected health, **including blood pressure monitoring**, requires a broad ecosystem of shared digital health information. PCHAlliance members span this entire ecosystem including entities that: manufacture the devices patients and providers use to measure biophysical data; provide health insights and increase the usability of clinical decision support; provide care; operate the networks that communicate patient generated data between patients and providers; and represent consumer perspectives on connected health. PCHA's member list can be found at <http://www.pchalliance.org>.

The NCA on Ambulatory Blood Pressure Monitoring (APBM), requested two types of input – scientific evidence and breadth of the review. We provide our input on each below.

Scientific Evidence:

As noted by the AMA and AHA letter that initiated this National Coverage Analysis (NCA), the published standard for care and the USPSTF recommendations, differ from the current NCD on ABPM. Both the AMA/AHA letter and the 2015 USPSTF recommendation on blood pressure screening provide extensive and significant citations for this review. We also recommend the NCA include and consider the extensive evidence available on ABPM for those with spinal cord injury (see below for citations and resources). We urge CMS to rely upon the AMA/AHA letter, the USPSTF Recommendation and the evidence cited below on the issues of orthostatic hypotension and autonomic dysreflexia in the spinal cord injury population for the NCA evidence review. Of particular note is the disconnect between the

NCD on ABPM and the current evidence-based standards of care – either that published by AHA/AMA or the recommendations issued by the USPSTF or those issued by the Consortium for Spinal Cord Medicine’s Clinical Practice Guidelines.

Additional Evidence to Consider Updating the NCD for ABPM for those with Spinal Cord Injury:

A number of meta-analyses and evidence reviews on cardiovascular health for those with spinal cord injury provide important information on clinical practice guidelines and the need for blood pressure monitoring and should be included in the NCA evidence review^{1,2,3,4,5,6,7,8}. Specifically, the “Consortium for Spinal Cord Medicine’s Clinical Practice Guidelines, Acute Management of Autonomic Dysreflexia: Individuals with Spinal Cord Injury, 2nd Edition states:

Autonomic dysreflexia (AD), with its sudden and severe rise in blood pressure, is a potentially life-threatening condition that can occur in anyone with a spinal cord injury (SCI) at or above thoracic level six (T6). (Foreword, p.v)

In addition, SCIRE, an international collaboration between scientists, clinicians and consumers, provides up-to-date, accurate information about the effects of rehabilitation healthcare for people with SCI. The following two links focus on blood pressure and cardiovascular health for those with spinal cord injury:

- <https://scireproject.com/evidence/rehabilitation-evidence/orthostatic-hypotension/introduction-ortho-hypo/>
- <https://scireproject.com/evidence/rehabilitation-evidence/autonomic-dysreflexia/introduction/>

¹ Consortium for Spinal Cord Medicine’s Clinical Practice Guidelines, Acute Management of Autonomic Dysreflexia: Individuals with Spinal Cord Injury Presenting to Health-Care Facilities, 2nd Edition

² A systematic review of the management of orthostatic hypotension after spinal cord injury. Krassioukov A, Eng JJ, Warburton DE, Teasell R; Spinal Cord Injury Rehabilitation Evidence Research Team. Arch Phys Med Rehabil. 2009;90:876-85.

³The Economic Burden of Autonomic Dysreflexia during Hospitalization for Individuals with Spinal Cord Injury. Squair JW, White BA, Bravo GI, Martin Ginis KA, Krassioukov AV. J Neurotrauma. 2016 Aug 1;33(15):1422-7. doi: 10.1089/neu.2015.4370. Epub 2016 Mar 22.

⁴ Acute management of autonomic dysreflexia: individuals with spinal cord injury presenting to health-care facilities J Spinal Cord Med. 2002 Spring;25 Suppl 1:S67-88.

⁵ Influence of the neurological level of spinal cord injury on cardiovascular outcomes in humans: a meta-analysis. West CR, Mills P, Krassioukov AV. Spinal Cord. 2012 Jul;50(7):484-92. doi: 10.1038/sc.2012.17. Epub 2012 Mar 6. Review.

⁶ Cardiovascular function in individuals with incomplete spinal cord injury: a systematic review. West CR et al. Top Spinal

⁷ Rehabilitation medicine: 1. Autonomic dysreflexia. Blackmer J et al. CMAJ. (2003)

⁸ Melville S. Byrd JB. Out-of-Office Blood pressure Monitoring in 2018. JAMA. 2018;320 (17):1805-1806.

Evidence Support for Technology Neutral Coverage Policy: While the literature notes that ABPM is the ‘gold’ standard for diagnosing abnormal blood pressure and identifying the most appropriate intervention or therapy for its treatment, it is also clear that improved technology allows supports for “home-based” blood pressure monitoring (HBPM) as an alternative.⁹ The USPSTF found adequate evidence to support home-based blood pressure monitoring, and, with technology improvements and the establishment of international blood pressure monitoring standards¹ there is little distinction between ABPM and HBPM. As technology improves, we expect:

- Biophysical data, such as blood pressure measurement, will be securely delivered to provider EHRs or digital monitoring platforms on a near real time basis; and,
- Blood pressure measurement devices that measure over a 24-48 hour period will be less disruptive to a patient’s daily life, while providing accuracy that meets international professional standards.

The NCD definition of ABPM should be modified as it requires use of old, cumbersome data capture technology and by deleting the phrase “**These 24 hour measurements are stored in the device**”. This part of the current NCD definition of ABPM reflects technology of 2001/2003, rather than today’s internet of things and interoperability standards which allow for wireless, near real time, transmission of blood pressure data.

We also recommend that the NCA consider the evidence and professional consensus that underlies the most recent AMA CPT Editorial Summary of Panel Actions from September 2018.¹⁰ During that CPT Editorial Panel meeting, the evidence base and professional society consensus strongly supported CPT approval of new codes for Self-Measured Blood Pressure Monitoring (CPT Codes 99X01 and CPT 99X02; with code revision for CPT 93784) to allow for the reporting of self-measured blood pressure monitoring to take effect January 1, 2020.

We urge CMS to define and ensure that ABPM coverage is technology neutral and allows for coverage of any blood pressure monitoring technology that demonstrates accuracy and delivery of accurate biophysical data to the provider who ordered the blood pressure monitoring.

Breadth of the Review:

The evidence base and standards of care for diagnosis and treatment of abnormal blood pressure support an NCA review of a number of indications for ABPM, beyond “white coat syndrome”, and NCA review should consider its use for:

⁹ Melville S, Byrd JB. Out-of-Office Blood Pressure Monitoring in 2018. JAMA. 2018;320(17):1805–1806. doi:10.1001/jama.2018.14865

¹⁰ Source: <https://www.ama-assn.org/sites/default/files/media-browser/public/physicians/cpt/september-2018-summary-panel-actions.pdf>

- Diagnosis of hypertension (use upon a single high blood pressure measure at or in a clinical setting);
- Masked hypertension for those patients with high CVD risk;
- Nocturnal blood pressure for those patients with a need for such measure;
- Review of treatment efficacy for those who may be at risk of overtreatment; and,
- Diagnosis and treatment of orthostatic hypotension and automatic dysreflexia – cardiovascular disease issues for those with spinal cord injury (see citations for standard of care and meta-analyses in evidence review section of this letter).

We appreciate the opportunity to provide information and are excited that CMS is engaging in an NCA to update its coverage policy for ABPM. This NCA has the potential to build and advance evidence-based blood pressure monitoring and interoperability. Patients need and expect our health care system to operate with 21st century technology that enables patient-provider electronic communication.

Please contact me if you need any additional information or have questions. The Personal Connected Health Alliance welcomes the opportunity to work with CMS as these and other exciting regulatory and policy changes are under consideration.

Sincerely,



Rob Havasy
Executive Director, Personal Connected Health Alliance

ⁱ *Validation protocols for blood pressure measuring devices in the 21st century.* George S. Stergiou MD, PhD, FRCP Bruce S. Alpert MD Stephan Mieke PhD Jiguang Wang MD, PhD Eoin O'Brien MD, DSc, FRCP. First published: 13 July 2018 <https://doi.org/10.1111/jch.13294>