ConnectedHealth

May 9, 2019

Attn: CAG-00067R2
The Honorable Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: *Proposed National Coverage Determination for Ambulatory Blood Pressure Monitoring* (Administrative File: CAG-00067R2)

The Connected Health Initiative (CHI) appreciates the opportunity to provide input on the Centers for Medicare & Medicaid Services' (CMS) *Proposed Decision Memo for Ambulatory Blood Pressure Monitoring (ABPM) (CAG-00067R2)* dated April 9, 2019.[1]

CHI is the leading effort by stakeholders across the connected health ecosystem to responsibly advance the use of digital health innovations in the prevention and treatment of disease, supporting an environment in which patients and consumers can see improvements in their health. We seek essential policy changes that will help all Americans benefit from an information and communications technology-enabled healthcare system. For more information, see www.connectedhi.com.

CHI is a longtime active global advocate for the increased use of new and innovative digital health tools in both the prevention and treatment of disease, particularly for chronic conditions such as high blood pressure. Additionally, CHI is an appointed member of the American Medical Association's (AMA) Digital Medicine Payment Advisory Group, an initiative bringing together a diverse cross-section of 15 nationally recognized experts that identifies barriers to digital medicine adoption and proposes comprehensive solutions revolving around coding, payment, coverage, and more.[2] CHI is also a board member of Xcertia, a collaborative effort to develop and disseminate mHealth app guidelines that can drive the value digital health products bring to the market and the confidence that physicians and consumers can have in health apps and their ability to help people achieve their health and wellness goals.[3]

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[1] https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=294.

[2] https://www.ama-assn.org/delivering-care/digital-medicine-payment-advisory-group.

[3] http://www.xcertia.org/.

In its Proposed Decision Memo, CMS proposes that evidence justifies ambulatory blood pressure monitoring (ABPM) being deemed reasonable and necessary for the diagnosis and management of hypertension in certain Medicare beneficiaries with suspected masked hypertension, to be covered once per year per patient. Supported ABPM devices would be quality-certified and validated for use in the intended patient population, capable of producing standardized plots of blood pressure measurements for 24 hours with daytime and nighttime windows and normal blood pressure bands demarcated, provided to patients with oral and written instructions and a test run in the physician's office must be performed, and read by the treating physician or treating non-physician practitioner.

CHI generally supports further coverage expansions to help Medicare beneficiaries realize the improved outcomes that remote patient monitoring technology can provide. CHI supports CMS' proposal to expand coverage for ABPM that tracks patients outside of the doctor's office, and agrees that such an extension is supported by a strong evidence base. The use of remote patient monitoring tools for Medicare beneficiaries with suspected masked hypertension, in addition to beneficiaries suspected of white coat hypertension, will assist in the detection of high blood pressure that would otherwise be missed, preventing mortality, stroke and cardiovascular disease, kidney disease, and other diseases.

However, the CHI urges CMS to avoid locking in a limited set of technologies for ABPM use through a restrictive definition. Many technologies exist today, and will further be developed in the future, that will enable the reliable tracking of ABPM within the parameters that CMS puts forward. We are concerned that the proposed definition of an eligible ABPM device may be interpreted to include legacy, single-purpose devices to the exclusion of innovative devices that utilize the latest in physiologic sensing, paired with an active internet connectivity-enabled feedback loop, enabling care planning and coordination augmented by predictive analytical technology, and, if necessary, streamlined interventions that save lives. The reliability of an ABPM device is no longer correlated to whether the data it collects is stored locally in the device for later interpretation by a caregiver. CHI further notes that CMS' analysis and conclusions under its ABPM-specific assessment questions addressing improved outcomes are aligned with this broader vision of eligibility for ABPM devices. CHI therefore requests that CMS clarify in its Determination that it contemplates eligibility for the range of connected devices capable of providing 24 hour measurements of ABPM for transmission, including combination devices enabling reliable ABPM that utilize secure cloud-based storage to provide collected ABPM data to clinicians for review. CMS should delete the requirement for ABPM data to be "stored in the device" from the proposed Item/Service Description in Appendix C (the edit being: "These 24-hour measurements ~~are stored in the device and~~ are later interpreted by the physician.").

CHI appreciates the opportunity to submit its comments to CMS. We look forward to assisting CMS in realizing a technology-enabled care continuum that provides maximum value to patients at the lowest costs.

Sincerely,

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