



May 9, 2019

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

Re: (CAG-0067R2) Proposed Decision Memo for 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 comment on the CMS Proposed Decision Memo for Ambulatory Blood Pressure Monitoring (ABPM). Our comment supplements the information we provided to support CMS' review, analysis and update of its National Coverage Decision (NCD) on Ambulatory Blood Pressure Monitoring on November 8, 2018. We believe that updating the Medicare ABPM National Coverage Decision (NCD) to reflect current evidence-based standards of care and technology is essential to enable providers to deliver effective, efficient and patient centered care to Medicare beneficiaries. Our comments, both in this letter and our 11/8/18 comment submission, focus on updating of both the covered indications and the definition of ABPM to ensure it is technology neutral.

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>.

We have several brief comments on the proposed national coverage decision on ABPM, and refer CMS back to our 11/8/18 comment letter which included extensive citations:

- ***We support and appreciate the revised specifications for ABPM devices*** so that providers may use any quality certified device from which periodic blood pressure measurement data is directly communicated to the cloud and/or to a provider data monitoring platform and/or to the provider maintained electronic health record. We applaud CMS for eliminating the old NCD requirement for a dedicated receiver to be part of a qualified ABPM device. The proposed APBM device specifications are technology neutral as drafted and this allows both innovation and provider choice of device.

- **We urge CMS to clarify the relationship between this coverage decision and self-measured blood pressure monitoring.** As we noted in our 11/8/18 comments, the AMA’s CPT Editorial Committee has created two new CPT codes on self-measured blood pressure monitoring that align with the evidence base and the USPSTF recommendations for home blood pressure monitoring for diagnosis of hypertension. Today’s technology allows for 24-hour, day and night, blood pressure monitoring to be digitally recorded and shared (OR to be manually recorded and shared), how does this coverage decision relate to the new CPT codes?
- **We request CMS provide more direction** on the “C. Other Indications” portion of the proposed coverage decision and suggest that CMS list examples of what could be considered but is not currently a listed example of an “other indication.” For example, in our 11/8/19 comment letter, PCHAlliance noted peer reviewed literature (7 citations) and standards of care (1 citation) for use of ABPM for those with spinal cord injury. In our experience, the publication of an NCD leads to use of the specified service/technology ONLY for the specified indications, and a presumption that all other indications are not covered. Without clarity and clear direction on what “other indications” may include, clinically appropriate evidence-based use will be curtailed.
- **We note that the specified indications for ABPM are extremely narrow and do not align with the USPSTF** recommendations or with the AHA/AMA letter requesting revision of this NCD. This is a concern as it will lead to underuse of APBM compared to the standard of care. We urge CMS to broaden the use of ABPM for the full range of indications supported by the literature OR to clarify that it will cover self-measured home blood pressure monitoring for the full range of indications for which 24-hour blood pressure monitoring is indicated.

We appreciate the opportunity to provide information and are excited that CMS is updating its coverage policy for ABPM. This NCD 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