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- 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 at reasonable cost in the

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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:

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 monitorin