Medicare Coverage Advisory Committee – Evaluative questions on portable devices that measure the same sleep and respiratory parameters as facility based polysomnography, i. e. EEG, EOG, EMG, respiratory movement, airflow, oxygen saturation, and heart rate or ECG.

1. How well does the evidence address the effectiveness of this type of unattended portable multi-channel home sleep testing devices as an alternative to facility-based polysomnography in the diagnosis of obstructive sleep apnea (OSA)?

*1 – Poorly * 2 * 3 – Reasonably Well * 4 * 5 – Very Well*

	2. How confident are you in the validity of the scientific data on the following outcomes? *1 - No Confidence* *2* *3 - Moderate Confidence* *4* *5 - High Confidence*	**3. How likely is it that these home sleep testing devices will be as good as or better than facility-based polysomnography for the following outcomes?** *1 – Not Likely* *2* *3 – Reasonably Likely* *4* *5 – Very Likely*
a. Acquisition of interpretable data		
b. Ability to accurately diagnose OSA (sensitivity)		
c. Ability to accurately identify those without OSA (specificity)		

4a. How confident are you that these sleep testing devices are as accurate in the diagnosis of obstructive sleep apnea as is a facility-based test?

*1 – No Confidence * 2 * 3 – Moderate Confidence * 4 * 5 – High Confidence*

4b. How confident are you that use of these sleep testing devices in the diagnosis of obstructive sleep apnea will lead to similar or improved health outcomes measured either directly or indirectly through changes in patient management?

*1 – No Confidence * 2 * 3 – Moderate Confidence * 4 * 5 – High Confidence*

4c. How confident are you that these sleep testing devices are as accessible as is a facility-based test for the diagnosis of obstructive sleep apnea?

*1 – No Confidence * 2 * 3 – Moderate Confidence * 4 * 5 – High Confidence*

5. Based on the literature presented, how likely is it that the evidence addressing the diagnosis of OSA utilizing these sleep testing devices can be generalized to:

*1 – Not Likely * 2 * 3 – Reasonably Likely * 4 * 5 – Very Likely*

a. The Medicare population (aged 65+): ☐

b. Providers (facilities/physicians) in community practice: ☐

Medicare Coverage Advisory Committee -- Evaluative questions on portable devices that measure cardiorespiratory parameters only, i. e. respiratory movement, airflow, oxygen saturation, and heart rate or ECG.

1. How well does the evidence address the effectiveness of this type of unattended portable multi-channel home sleep testing devices as an alternative to facility-based polysomnography in the diagnosis of obstructive sleep apnea (OSA)?

*1 – Poorly * 2 * 3 – Reasonably Well * 4 * 5 – Very Well*

	2. How confident are you in the validity of the scientific data on the following outcomes? *1 - No Confidence* *2* *3 - Moderate Confidence* *4* *5 - High Confidence*	**3. How likely is it that these home sleep testing devices will be as good as or better than facility-based polysomnography for the following outcomes?** *1 – Not Likely* *2* *3 – Reasonably Likely* *4* *5 – Very Likely*
a. Acquisition of interpretable data		
b. Ability to accurately diagnose OSA (sensitivity)		
c. Ability to accurately identify those without OSA (specificity)		

4a. How confident are you that these sleep testing devices are as accurate in the diagnosis of obstructive sleep apnea as is a facility-based test?

*1 – No Confidence * 2 * 3 – Moderate Confidence * 4 * 5 – High Confidence*

4b. How confident are you that use of these sleep testing devices in the diagnosis of obstructive sleep apnea will lead to similar or improved health outcomes measured either directly or indirectly through changes in patient management?

*1 – No Confidence * 2 * 3 – Moderate Confidence * 4 * 5 – High Confidence*

4c. How confident are you that these sleep testing devices are as accessible as is a facility-based test for the diagnosis of obstructive sleep apnea?

*1 – No Confidence * 2 * 3 – Moderate Confidence * 4 * 5 – High Confidence*

5. Based on the literature presented, how likely is it that the evidence addressing the diagnosis of OSA utilizing these sleep testing devices can be generalized to:

*1 – Not Likely * 2 * 3 – Reasonably Likely * 4 * 5 – Very Likely*

a. The Medicare population (aged 65+): ☐

b. Providers (facilities/physicians) in community practice: ☐

Question #2 includes the term "validity." CMS uses "validity" here as defined by Meinert, "Validity, in the context of a treatment difference, refers to the extent to which that difference can be reasonably attributed to a treatment assignment." (Meinert CL. Clinical Trials, Overview. In: Redmond CK, Colton T, eds. Biostatistics in Clinical Trials. Wiley and Sons, 2001. pp. 37-51). This encompasses all issues of methodologic framework, study design, observed results, biological rationale, etc.

Question #2 includes the term "acquisition of interpretable data." CMS defines this term as the absolute number or percentage of patients whose results could not be evaluated due to loss of data for any reason. Mode of technician assistance in appropriate device set-up should also be considered and includes the following 3 scenarios:

1) technician initiated application of the device in the laboratory setting
2) technician initiated application of the device in the home setting
3) technician instructions only, with patient application of the device

Question #3 and #4 includes the term "accurate/accurately". The standard measures of accuracy are sensitivity (probability of a positive test result in a patient with a disease or risk factor or other health condition) and specificity (the probability of a negative test result in a patient who does not have the disease). Ideally a new test would increase both sensitivity and specificity.