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**Re:** Obstructive Sleep Apnea National Coverage Determination

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The following is a request to reassess the national coverage determination for diagnosis and treatment of obstructive sleep apnea (OSA) to include multichannel home sleep testing as an alternative to polysomnography (PSG).

1. The term sleep disordered breathing (SDB) is used synonymously with the older term OSA. SDB is a prevalent, morbid, mortal illness affecting 24% of adult males and 9% of adult females using an AHI of  $\leq 5$  and affecting 4% of adult males and 2% of adult females using an AHI of  $\leq 15$ . SDB is associated with hypertension, heart attack, stroke, heart failure, cardiac arrhythmia, nocturia, gastroesophageal reflux disease, asthma, obesity, diabetes and early death. SDB causes daytime sleepiness, increased motor vehicle and job related accidents and detracts from “feeling well” and functioning well at home and at work.

This request is especially important for Medicare patients as 80% of patients with heart failure have SDB and benefit substantially from CPAP therapy.

2. SDB is grossly under diagnosed in large part due to a limited number of sleep diagnostic facilities.
3. This request focuses on the importance of multichannel home sleep testing as an alternative to the traditional in house polysomnography currently required by CMS.
4. In house PSG has its troubles:
  - a. Patients sleep in a Lab as compared to testing in their own home and bed.
  - b. Many employ split night studies so 2-4 hours are devoted to diagnosis and 2-4 hours are devoted to setting a CPAP titration pressure, inadequate time periods for both studies.
  - c. PSG uses the same respiratory detectors, oximeter, chest and abdomen sensors and position sensors, as do multichannel home sleep tests.

- d. PSG provides EEG information regarding arousals yet this information has high interpreter variability and ultimately diagnoses are made first by the respiratory information, second by the patient's history and physical examination, and third by the oximetry recordings. So in fact, EEG and arousals make little difference. Sleep stages, time and efficiency are useful information, but not necessary to make a diagnosis.
5. Multichannel home sleep tests:
  - a. Use the same respiratory equipment and analysis as do PSG.
  - b. Use the same oximetry equipment and analysis as do PSG.
  - c. Use the same chest and abdominal equipment as do PSG.
  - d. Use the same position sensors as do PSG.
  - e. Report the same AHI except uses a denominator of total time in bed, rather than total time asleep, which for these with SDB seems not to be an issue.
6. Therefore, the outputs from PSG and multichannel home sleep tests are not very different.
7. Multichannel home sleep tests have several advantages over PSG:
  - a. They are performed in one's own home, bed and privacy.
  - b. The wires, leads etc., are less numerous and the patient's sleep is more comfortable and therefore more indicative of their normal sleep.
  - c. Multichannel home sleep tests are substantially less expensive; 25 to 30% the cost of PSG.
  - d. Multichannel home sleep diagnostic equipment is less expensive than PSG setups and equipment.
  - e. Multichannel home sleep diagnostic dispensing and titration is far easier than PSG lab setups and therefore can be performed by a greater number of practitioners, such as ENT surgeons, cardiologists, primary care physicians and others.
8. If PSG is in fact the most accurate sleep diagnostic paradigm (this issue is easily argued to the converse) are multichannel home sleep tests sufficiently accurate to be used for routine sleep apnea/SDB cases?
9. It appears that the primary focus of discussion pro PSG is the efficacy of PSG vs. multichannel home sleep testing. There are numerous validation studies of multichannel home sleep testing versus PSG.

There are **14** studies involving 747 patients using **8** different multichannel home sleep tests in **10** different countries, which demonstrate excellent correlation between multichannel home sleep testing and PSG. There are no reports of poor correlations, error in diagnosis or adverse events as a result of multichannel home sleep testing in these studies.

Therefore, it is proposed that the portable multichannel home sleep test be used as an alternative for polysomnography performed in a sleep laboratory in the evaluation of OSA.