American Academy of Sleep Medicine

Testimony Before the Medicare Evidence and Development and Coverage Advisory Committee (MedCAC) on its National Coverage Determination Continuous Positive Airway Pressure for Obstructive Sleep Apnea
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My name is Alex Chediak, and I am the president of the American Academy of Sleep Medicine. I am also Medical Director of Miami Sleep Disorders Center in South Miami, Chief of the Sleep Disorders Center at Mount Sinai Medical Center in Miami Beach, the largest private, independent, not-for-profit teaching hospital in South Florida, and Associate Professor of Medicine at the University of Miami at Mount Sinai. In these roles I diagnose and treat patients with sleep disorders, perform clinical research and teach house officers and fellows.

The AASM appreciates the opportunity to comment on the MedCAC review of the national coverage decision on continuous positive airway pressure therapy (CPAP) for OSA, and we commend the Centers for Medicare and Medicaid Services (CMS) for its wisdom in adhering to scientific evidence for determining national coverage determination (NCD) policies.

The request letter submitted by the American Academy of Otolaryngology contends that the diagnosis of patients with sleep disordered breathing is limited because facility based-polysomnography (PSG) is "not widely available". While this might be the case in some countries, this statement is inconsistent with the data pertaining to sleep testing availability across the United States. A study based on 2001 data estimated that 427 polysomnograms were performed per year per 100,000 population (1). Since 2001, the number of sleep facilities accredited by the AASM has more than doubled to 1,266 with 259 applications having been received in just the first six months of 2007. An independent survey by Shariq (2) estimated there were more than 2,500 accredited and non-accredited sleep facilities in the U.S. in 2004 with an average wait time for a PSG between 2 and 3 weeks. In a 2005 survey of U.S. sleep centers by Wachovia Securities they report a 27% increase in sleep center bed capacity over the previous year and an AASM survey conducted in 2004 there was an average wait of about 3 weeks for a sleep study or sleep consultation. Most recently the AASM surveyed accredited sleep facilities and found a decrease in PSG and consultation wait time to a median of 12 and 14 days, respectively. Considering that not all sleep testing sites are accredited by the AASM, the available sleep testing opportunities derived from surveys limited to AASM-accredited sites necessarily overestimate the wait time for PSG and sleep physician consultation.

We conclude that in the United States, as a whole, patients do not have unacceptable delays in accessing sleep consultations or PSG. Furthermore, the number of accredited sleep centers continues to grow and current data suggest that increasing demand will be met by appropriate increased supply.

Having established the ready supply of sleep facilities across the country and the very reasonable patient wait times for an initial consultation and PSG, the availability of data on unattended PM for the diagnosis of OSA must be considered.

In 2003, the AASM, in association with the American College of Chest Physicians (ACCP) and the American Thoracic Society (ATS) published "Practice Parameters for the Use of Portable Monitoring Devices in the Investigation of Suspected Obstructive Sleep Apnea in Adults." (3) Based on limited data showing highly variable and questionable performance, the published joint guideline of the three societies did not recommend unattended portable monitoring (PM) for diagnosing OSA. This AASM/ ACCP/ ATS paper was updated in a September 1, 2004 report commissioned by the Agency for Healthcare Research and Quality (AHQR) whom reported that "This newer body of evidence does not materially change earlier findings regarding in-home devices for diagnosing OSA."

Dr. Nielsen of the American Academy of Otolaryngology in his letter cites three additional studies that were conducted recently (4) (5) (6) as well as the 2007 study by Mulgrew et al (7). It is notable that all four studies were performed outside the United States in countries with very different health care systems. Two of the four studies did not assess portable monitoring to diagnose OSA. All protocols were carried out by specialists in sleep medicine at academic sleep centers and in populations that are not representative of Medicare beneficiaries (Mean age of approximately 50 years).

In summary, two recent studies provide some evidence in support of portable monitoring for the diagnosis of OSA in selected patient groups with high pre-test probabilities of OSA who are managed intensively in academic centers by sleep specialists. Medicare demographics were not well represented in these studies and the results cannot be extrapolated to primary care or surgical practices. Further studies are needed to confirm these results and to determine whether these approaches are cost-effective as compared to PSG. They do not warrant a change in the CMS NCD 240.4.

Obstructive sleep apnea should be diagnosed by a combination of clinical history, physical examination and recording of patients' sleep. Such a comprehensive approach by physicians trained and experienced in sleep medicine is necessary to avoid over diagnosis of the condition and unnecessary treatment, as well as to determine the presence of other sleep disorders that may substantially contribute to the patients' symptoms. The follow up of patients after sleep studies is equally important. Patients should receive a diagnosis of OSA from a sleep specialist experienced in providing different options for therapy with thorough explanations of the advantages and disadvantages of each. OSA is a chronic disorder and patients should be followed in an AASM accredited sleep medicine facility or by a physician board certified in

sleep medicine. Without such follow up, compliance with expensive therapies is likely to be poor. This was illustrated by a national survey published last year which demonstrated that patients who were evaluated and treated by board certified sleep specialists at AASM accredited sleep centers had superior outcomes (8).

It is essential that sleep studies be read and interpreted by specialists trained and experienced in their use, and this is especially true for PM studies. According to the 2004 AHRQ report (9), the overall proportion of home studies with inadequate data due to artifact and sensor displacement averaged 13 percent and data loss was as high as 33 percent when the patients performed the hookup. A draft AHRQ report from 2007 similarly describes high rates of unsatisfactory studies and data corruption for PM in the home setting compared to facility-based PSG, or PM in the sleep laboratory setting.

Considering these factors, the use of such devices by physicians untrained in their appropriate use and especially in the visual analysis of the raw signal that is required in order to properly validate the data, will result in a significant proportion of serious misdiagnoses. This will be compounded if such health care providers do not have the skills to interpret the study results in terms of the patient's individual clinical sleep history. The result of indiscriminant availability of reimbursement for portable monitoring will affect diagnostic accuracy in an unpredictable manner with potential for both inappropriate therapy and added costs. In support of the latter, the 2006 study of Ghegan et al (10), using over 1,200 patient profiles in four different treatment settings, concluded that PM actually costs more than PSG, in part because it is often necessary to repeat testing with PM due to technical difficulties or lost data. Medicare beneficiaries have higher prevalence of comorbid medical and sleep disorders, conditions known to reduce the diagnostic reliability of PM and the Medicare population is generally underrepresented in PM studies. It follows that the existing data on PM failure probably underestimates PM failure rates should PM be widely adopted in the Medicare population.

MedCAC should be aware of three ongoing initiatives aimed at elucidating the role of PM in the diagnosis and management of adult OSA. Perhaps the most important of these is the American Sleep Medicine Foundation grant to Drs. Carol Rosen and Susan Redline of the Case Western Reserve for a large, multi-center trial that will compare PM to diagnose OSA followed by CPAP (dose derived by auto-titrating PAP used at home) with PSG and CPAP derived by split night PSG. Following a paradigm designed to mimic actual practice scenarios, this study aims to examine both clinical and economic outcomes. The results from this grant are expected before June 2009. The Veterans Administration has funded a similar multi-center grant that is now actively collecting data in Pittsburgh and Philadelphia. Finally, the AASM, ATS, ACCP and the European Respiratory Society workshop entitled "Research Priorities in Portable Monitoring" is scheduled to take place October 14-16 2007 in Washington, DC.

Given ongoing initiatives, the lack of substantive new evidence to support the widespread use of PM to diagnose OSA, and concern over the applicability of the evidence to the Medicare population, it remains our position that if PM is to be used in the future for diagnosis of obstructive sleep apnea, it should be restricted to studies performed under the construct of AASM-accredited sleep facilities or by board certified sleep specialists.

MedCAC requested comment on the empiric use of CPAP without prior diagnostic PSG or PM. To our knowledge, only the study by Senn et al.(5) addresses this paradigm and it is flawed by the lack of randomization and any control group. The widespread use of this approach is ill advised and potentially harmful to Medicare beneficiaries.

NCD 240.4 is based on an apnea-hypopnea index (AHI) recorded during a minimum of two hours of sleep. This criterion allows adequate studies to be performed for the majority of patients with OSA. However, there exists a minority of patients with severe OSA with so many arousals from respiratory events that it is difficult to obtain two hours sleep in the first half of the night under a split-night protocol and occasionally even with a full night diagnostic PSG. For these patients, a modification of the criteria may be appropriate to allow for single night studies with a diagnostic portion followed by a CPAP titration portion to be performed.

The AASM would be supportive of a change in the NCD 240.4 criteria to read: "...The AHI is equal to the average number of episodes of apnea and hypopnea per hour and must be based on a minimum of 2 hours of sleep recorded by PSG using actual recorded hours of sleep (i.e., the AHI may not be extrapolated or projected). If the actual number of apneas and hypopneas recorded is 30 or more, then less than 2 hours sleep is acceptable, as long as at least 2 hours polysomnographic recording in bed has been obtained." The AASM is aware that there are no available data to estimate what proportion of patients would be impacted by such a change in strategy, whether such a change would be cost effective, or whether it would affect outcomes. Thus, while we would support this modification of criteria, we recognize that this is based on expert consensus regarding the welfare of a minority of patients and not on published evidence.

In closing, the AASM is not opposed to the development and application of new technologies that will be of benefit to the patients we serve. While we acknowledge the limited new evidence that supports use of PM in highly selected patient populations intensively managed by sleep specialists in academic sleep centers, the existing body of evidence remains inadequate to warrant changing NCD 240.4 allowing for widespread use of PM to diagnose OSA. We eagerly await the results of the ASMF and Veterans Administration multi-center trials on PM to provide the evidence for making rational decisions regarding home use of PM in the management of adult OSA.

Thank you for allowing us the opportunity to comment on this highly important issue. We would be very willing to provide any further clarifications that may be helpful to both the MedCAC panel and CMS.

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