

The American Academy of Sleep Medicine (AASM) welcomes the opportunity to provide comments regarding the Proposed Decision Memo for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (CAG-00093R2).

Home sleep testing (HST) was first considered by the Centers for Medicare & Medicaid Services (CMS) in 1989, and subsequently in 1995, 2001, 2005 and 2007. Each time the issue was addressed by CMS, the AASM, as the professional society representing almost 7,000 sleep medicine specialists, provided a formal comment based on the evidence available at the time. The AASM stands by its comments and its commitment to evidence-based medicine.

The AASM has raised a number of concerns throughout this most recent process regarding the evidence CMS used as the base for this proposed decision. The AASM has noted that the studies cited in the proposed draft did not include the patient population covered by Medicare. Additionally, the evidence included in the proposed decision, as the AASM has also noted, is from controlled studies which were all conducted by sleep specialists in academic centers on highly selected study populations without co-morbidities who almost always had a high pre-test probability for OSA. Further, the AASM has raised the issue of high occurrences of false positive and false negatives associated with portable monitoring, especially Type IV monitors. While these concerns will not be repeated in detail within this comment, the AASM stands by its previous remarks and feel they remain relevant.

The AASM acknowledges that the proposed decision is broad. However, the AASM believes important topics are not addressed in the proposed decision:

1. Documentation of OSA and determination of severity by diagnostic testing is essential for proper management of patients with this disorder. Severity level is the best predictor of cardiovascular morbidity and predicts success with different modes of treatment, especially in those with severe disease. In-lab attended polysomnography provides the most accurate method for establishing a diagnosis of OSA and risk stratification as well as providing an opportunity to initiate CPAP in high risk individuals via a split-night protocol.
2. The proposed decision does not define an acceptable CPAP trial.
3. The proposed decision does not define the requirements for clinical evaluation that complements the HST.
4. The proposed decision does not define a paradigm for follow-up and long-term management, especially in patients with negative home study test or failed CPAP trials.
5. CMS must clarify who is covered by the NCD.
  - a. Does the NCD only affect beneficiaries enrolled in Medicare after implementation of the NCD?
  - b. Does the NCD affect all Medicare beneficiaries?
  - c. Does the NCD affect all Medicare beneficiaries who already utilize CPAP therapy?
6. The average life of a CPAP machine is 5 years. As such, will CMS require patients who utilize CPAP therapy to undergo an additional 12-week diagnostic period when a new machine is needed?

In the following comments the AASM addresses the medical-related topics cited 1 through 4 above as they will have an impact on patient care, and anticipate further comment from CMS on topics 5 and 6.

*CMS Proposed Decision 1: We are proposing that, due to the evidence demonstrating that no combination of diagnostic procedures adequately identifies all of those beneficiaries who will benefit from CPAP, the coverage of CPAP is initially limited to a twelve week period to identify beneficiaries diagnosed with OSA as subsequently described who benefit from CPAP. CPAP is subsequently covered for those beneficiaries diagnosed with OSA who benefit from CPAP during this twelve week period.*

**The AASM disagrees with recommendations within this decision as stated.**

The proposal fails to define the measures by which any physician, especially those inexperienced and untrained in sleep medicine, would assess the benefit of therapy and also does not call for long-term management through programs that emphasize education and follow-up care. This is of particular concern due to the lack of training in sleep medicine provided to physicians in both undergraduate and postgraduate training programs, as recently documented by the Institute of Medicine.<sup>1</sup>

The AASM believes that disease management by properly trained physicians board certified in sleep medicine is essential for the delivery of optimal care.

- 1) The AASM recommends that the diagnosis and treatment of OSA be performed under the supervision of a specialist board certified in sleep medicine.
- 2) Consistent with published literature, the AASM recommends that the measurement of acceptable CPAP adherence as use of CPAP for at least 4 hours of sleep for at least 70% of the days or an improvement in clinical symptoms.<sup>2</sup>
- 3) At the end of the 12-week trial period, the AASM recommends follow-up evaluation with the board certified sleep specialist for reassessment of clinical symptoms and a review of other potential treatment options if the beneficiary is unable to meet the minimum requirement for measurement of CPAP adherence. This may include in-lab polysomnography, repeat positive pressure titration or another CPAP trial after addressing problems limiting use.

The AASM supports the requirement for documentation of a relevant clinical evaluation as an essential component of the diagnosis of OSA. The proposed decision fails to specify what constitutes a “clinical evaluation.” As such, the AASM recommends that the NCD require the following criteria be part of the required clinical evaluation:

- Inquiry for symptoms of snoring, observed apneas and daytime sleepiness;
- A physical examination that includes a body-mass index and assessment of the nose, oropharynx, neck, lungs and cardiovascular system.
- Inquiry for other co-morbid sleep disorders that can adversely affect treatment of OSA.
- Inquiry for co-morbid medical disorders that can adversely affect treatment of OSA.

*Proposed Decision 2: We are proposing that the use of CPAP will be covered when diagnosed using a clinical evaluation and PSG performed in a sleep laboratory. In addition, we are proposing to expand coverage of CPAP to include those beneficiaries with a diagnosis of CPAP*

*made using a combination of clinical evaluation and unattended home sleep monitoring using a Type II, III or IV device.*

### **The AASM supports limitations on the use of unattended home sleep monitoring**

While the AASM supports the use of Type II and III HST devices by board certified sleep specialists in patients with a high pre-test probability of moderate to severe obstructive sleep apnea, it does not support the indiscriminate use of HST by physicians untrained in sleep medicine. The high rate of false positive and negative results, the high frequency of technical failure, the necessity to review the raw data from such devices, and the need for quality control processes will result in suboptimal patient care in the hands of inexperienced practitioners. Since the posting of the draft decision memo by CMS, the AASM published “Clinical Guidelines for the Use of Unattended Portable Monitors in the Diagnosis of Obstructive Sleep Apnea in Adult Patients”<sup>3</sup>; a copy of the guidelines is enclosed for your information.

The AASM suggests the following criteria for a “high pre-test probability of moderate to severe obstructive sleep apnea”: adjusted neck circumference > 43 cm (17 inches) **AND** the presence of excessive daytime sleepiness (Epworth sleepiness scale > 10). Adjusted neck circumference = neck circumference + 3 cm (if habitual snorer) + 4 cm (if hypertension present) + 3 cm (if apnea, gasping, choking most nights)<sup>4</sup>

In cases where HST is technically inadequate or fails to establish the diagnosis of OSA in patients with high pretest probability, beneficiaries should be evaluated in an AASM-accredited sleep facility with attended polysomnography

### **The AASM does not support Type IV devices for home sleep testing.**

Consistent with its clinical guidelines, the AASM supports Type II and III HST devices. However, the AASM does not support the inclusion of Type IV HST devices.

Type IV devices are one or two channel devices, typically including oxygen saturation and/or airflow. When moving from Type II and III HST devices to Type IV HST devices, the certainty of establishing a diagnosis of OSA can be greatly impacted. The proposed use of Type IV devices makes ripe the potential for substandard patient care and a substantial increase in unnecessary tests. The Proposed Decision Memo (page 24) states that for oximetry alone, “...the evidence reviewed does not demonstrate its utility in the diagnosis of OSA, and we cannot be confident that this diagnostic modality accurately identifies those patients with OSA who will respond clinically to CPAP and excludes those who will not.” A similar conclusion was reached by the AASM in its recently published document Clinical Guidelines.

*Proposed Decision 3: We are proposing to modify the criteria for a positive sleep study to remove the requirement for a minimum of two hours of continuous recorded sleep and instead recognize shorter periods of continuous recorded sleep if the total number of recorded events during that shorter period is at least the number of events that would have been required in a two hour period.*

**The AASM supports the recommendation.**

*Proposed Decision 4: We are proposing to delete the current distinct requirements that an individual have moderate to severe OSA and that surgery is a likely alternative because these terms are not sufficiently precise.*

**The AASM supports the recommendation.**

The AASM endorses the proposed decision to delete the current distinct requirements that an individual have moderate to severe OSA and that surgery is a likely alternative. Surgery has a useful but limited role in the management of OSA. The primary treatment modality for symptomatic OSA regardless of the apnea / hypopnea index (AHI) is CPAP. In these individuals, a trial of CPAP should be pursued.

*Proposed Decision 5: Due to a lack of sufficient evidence that clinical diagnosis alone or clinical diagnosis in combination with devices other than Type I, II, III, or IV adequately identify beneficiaries with OSA that will benefit from CPAP, we are proposing to expand Medicare coverage for CPAP in these instances only when provided in the context of a clinical study that meets standards set by CMS.*

**AASM accepts this recommendation for Coverage with Evidence Development and contends that it be extended to clinical research studies that involve Type I, II, III, IV and other devices, such as peripheral arterial tonometry, to encourage investigation into new methods of OSA diagnosis and provision of longitudinal care.**

Thank you for the opportunity to comment on the proposed decision. The AASM offers its expertise to CMS on the development of the final coverage determination and is willing to assist in any possible manner.

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<sup>1</sup> Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem, Colten HR (Chair) National Academies Press Washington, DC 2006

<sup>2</sup> Gay P, Weaver T, Loube D, Iber C; Positive Airway Pressure Task Force; Standards of Practice Committee; American Academy of Sleep Medicine. Evaluation of positive airway pressure treatment for sleep related breathing disorders in adults. *Sleep*. 2006;29:381-401.

<sup>3</sup> Collop NA, Anderson WM, et al. Clinical Guidelines for the Use of Unattended Portable Monitors in the Diagnosis of Obstructive Sleep Apnea in Adult Patients. *J Clinical Sleep Med*. 2007;7:737-747.

<sup>4</sup> Flemons WW, Whitelaw WA, Brant R, Remmers, JE. Likelihood Ratios for a Sleep Apnea Clinical Prediction Rule. *Am J Respir Crit Care Med*. 1994;150:1279-1285.