Why CMS Approved Home Sleep Testing for CPAP Coverage

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On December 14, 2007 the Centers for Medicare & Medicaid Services (CMS) released its proposed decision for modification of National Coverage Determination (NCD) policy 240.4 pertaining to coverage of continuous positive airway pressure therapy (CPAP) for adult obstructive sleep apnea (OSA). The proposed modification allows for an initial 12 week period of CPAP coverage when OSA is diagnosed using both a clinical evaluation and polysomnography performed in the sleep laboratory (PSG) or a clinical evaluation and unattended home sleep testing (HST) using a Type II, III or IV device. CPAP would be subsequently covered for those diagnosed with OSA who benefit from CPAP during the 12-week trial. CMS further intends to modify the criteria for a positive sleep study by removing the requirement for a minimum two hours of continuous recorded sleep (the 2-hour rule) and remove the current requirements that an individual have moderate to severe OSA and that surgery is a likely alternative to CPAP. Finally, CMS will expand Medicare coverage for CPAP for beneficiaries with a clinical diagnosis of OSA without either PSG or HST only when provided in the context of a clinical study that meets specific standards. A clinical study seeking Medicare coverage for CPAP pursuant to Coverage with Evidence Development must necessarily address specific questions as stipulated in the NCD.

Modifying the 2-hour rule as proposed is likely to be perceived favorably by all vested parties. However, allowing unattended HST to diagnose OSA has the potential to fundamentally change sleep healthcare delivery, economics and outcomes in ways that are difficult to confidently predict. The debate over the use of HST to establish the diagnosis of OSA began long before the 2007 CMS review of NCD policy 240.4. In fact, unattended HST has been reviewed by CMS since 1989 with subsequent reviews in 1995, 2001 and 2005. The most recent prior challenge to NCD 240.4 occurred in 2004 and culminated in April of 2005 with CMS opining that “…there is not sufficient evidence to conclude that unattended portable multi-channel sleep study testing is reasonable and necessary in the diagnosis of OSA for CPAP therapy, and these tests will remain non-covered for this purpose.” I was initially surprised by the CMS decision to include unattended HST in NCD 240.4, particularly without expert oversight of HST and a mandate for a well-defined comprehensive sleep evaluation. After thoughtful reflection on the proposed changes and the CMS coverage determination policy process, I intend to offer my personal insight on the proposed modifications of NCD 240.4 and on the message that CMS is sending to the sleep community. An appreciation of the events leading up to the 2007 decision is helpful in understanding the rationale behind the CMS decision. Therefore, I will begin with a brief historical overview.

In January 2007 Dr. David R. Nielsen, Executive Vice President and Chief Executive Officer of the American Academy of Otolaryngology-Head and Neck Surgery requested that CMS revise NCD 240.4. Among the challenges to the 2005 NCD policy included the notion that the diagnosis of OSA is restricted by requirement for PSG, a test described as expensive and not widely available. Further, Dr. Nielsen argued that HST was a validated, less costly alternative to PSG and that even less expensive paradigms for diagnosis and treatment were currently being explored and that HST was an important first step in promoting and working toward these alternatives.

The American Academy of Sleep Medicine (AASM) response to CMS by then-President Dr. Michael Silber included an appraisal of the literature on the availability of PSG across the United States, a survey of PSG and sleep specialist wait times in AASM accredited facilities and a review of the clinical and economic data on HST after the 2004 challenge to NCD 240.4. The AASM April 10, 2007 letter to CMS Director of Coverage and Analysis Group, Dr. Steve Phurrough, methodically established the factual basis for the following AASM positions:

1. The most recent data indicate that PSG is widely available in the United States.
2. There is no evidence to suggest that a change in the NCD policy for HST will have a significant effect on patient access.
3. Published studies up to 2004 have not provided evidence in support of HST for the diagnosis of OSA.
4. Subsequent to 2004, two studies provide some evidence in support of HST when used in highly selected cases and managed intensively in academic sleep centers.
5. Available data do not indicate that HST is more cost effective than PSG, especially taking into account technical failures, as well as false negative and false positive results.
6. Wide spread use of HST by physicians lacking training and/or experience in sleep disorders will likely result in adverse patient outcomes.
7. There is credible evidence that patients managed for OSA at AASM accredited sleep centers have better outcomes.
8. If HST is demonstrated in the future to be of utility in the
management of some patients suspected of having OSA, it will be necessary that such procedures be restricted to use in accredited sleep centers in order to ensure optimal patient care.

CMS used several sources of evidence in its decision to modify NCD 240.4. In addition to receiving commentary from professional societies, industry and individuals, CMS prepared for the decision by commissioning an external technology assessment from the Agency for Healthcare Research and Quality (AHRQ) to review published clinical evidence on the use of HST in the diagnosis of OSA; reviewed relevant published evidence based guidelines since 2003 and held a Medical Coverage Advisory Committee (MedCAC) meeting on September 12, 2007. Collectively, the evidence largely aimed to answer three fundamental questions regarding OSA and CPAP coverage. Firstly, CMS inquired if there is sufficient evidence to determine that diagnostic strategies other than facility based PSG accurately identify patients with OSA who will benefit from CPAP treatment. Secondly, they questioned the notion that at least two hours of continuous recorded sleep is necessary for the accurate diagnosis of OSA. Thirdly, CMS queried if a diagnosis of OSA by clinical criteria alone is sufficient for the use of CPAP.

The AASM testimony that I delivered to the MedCAC panel largely mirrored the April 10, 2007 AASM letter to CMS. Other professional societies providing testimony included the American Academy of Otolaryngology-Head and Neck Surgery (in favor of HST), American Association of Respiratory Care (spoke to the 2-hour rule), the American College of Chest Physicians (ACCP), and the American Thoracic Society (ATS). While there was variance in the degree of conviction, in general the AASM, ACCP and ATS testified against the indiscriminate use of HST. AASM member Dr. David Kuhlmann testified as a private individual and was supportive the AASM position. The sleep device and healthcare delivery industry representatives such as Ion Healthcare, Apria Healthcare, Freudman Health Consulting, Advanced Brain Monitoring, SNAP Laboratories, and others countered with their opinion that HST identified sleep-related breathing events similarly to PSG and that outcomes of patients diagnosed with OSA and treated with CPAP based on HST derived data was not worse than that when the diagnosis was based on data derived by PSG. The notion that PSG is the gold standard for diagnosing OSA was challenged along the lines that information derived from PSG (AHI, arousals, sleep and desaturation variables) correlate only weakly with symptom severity, response to CPAP therapy, utilization of CPAP and prognosis. Among the industry consultants and/or executives testifying in support of HST were AASM members Dr. Mark Goetting and AASM Past Presidents Drs. William Dement and Philip Westbrook. In essence, the MedCAC panel members were exposed to widely divergent opinions regarding the value of PSG and HST in the diagnosis of OSA and as a predictor of outcomes after treatment with CPAP. The panel expressed moderate to high confidence on the evidence used to determine if clinical evaluation and PSG can accurately diagnose OSA, moderate confidence on the evidence for clinical evaluation and HST and less confidence on the evidence for clinical evaluation alone. In regards to the accuracy of strategies used to diagnose OSA, the MedCAC panel expressed strong moderate to high confidence for a clinical evaluation combined with PSG, strong to moderate confidence for a clinical evaluation with a Type II HST, moderate confidence for a clinical evaluation with a Type III HST and less than moderate confidence for both a clinical evaluation with a Type IV HST and a clinical evaluation alone. Considering the value of a clinical evaluation alone or combined with either PSG or HST to predict CPAP use, the panel expressed moderately high confidence when combined with PSG, moderate confidence when combined with HST and low confidence in a clinical evaluation alone. Finally, the panel expressed low to moderate confidence that a trial of CPAP without prior PSG or HST would not produce clinically meaningful harm.

Considering that in general the MedCAC panel and AHRQ technology assessment review expressed greater diagnostic confidence in PSG than in HST (particularly in Type IV HST devices), what prompted CMS to allow HST in the diagnostic paradigm for CPAP coverage determination? Simply stated, CMS approached the 2007 decision on NCD 240.4 in a manner fundamentally distinct from earlier reviews. In contrast to the 2005 CMS decision where diagnostic accuracy was the primary determinant of CPAP coverage, in 2007 CMS deemphasized diagnostic accuracy in lieu of strategies more apt to predict favorable outcomes for treatment of OSA with CPAP. Since the available evidence does not confidently establish that indices derived from either PSG or HST can be used to reliably predict treatment outcomes in OSA patients treated with CPAP, neither could be specifically excluded from the coverage determination policy. The relative value of treatment outcome over diagnostic accuracy as the primary determinant of CPAP coverage is consistent with the CMS proposal to link long-term coverage for CPAP to demonstrable benefit after a 12-week trial of CPAP. Finally, the language of the proposed decision suggests that CMS is seeking evidence to add benefit from CPAP among the reasonable and necessary prerequisites to a diagnosis of OSA for CPAP coverage determination purposes.

CMS has not excluded PSG as reasonable and necessary for the diagnosis of OSA and makes no provision on the mechanism of CPAP titration. The proposed modification of NCD 240.4 does not specifically address management strategies after a failed home CPAP trial in patients diagnosed with OSA by clinical evaluation and HST. In this regard, PSG remains necessary in the diagnosis and management of OSA. However, in mandating benefit from CPAP as reasonable and necessary for continued coverage of therapy, is CMS encouraging the medical community in general and sleep medicine in particular towards a chronic care approach to OSA? Many patients with OSA have coexisting sleep disorders such as insomnia and residual sleepiness despite appropriate CPAP therapy, conditions that increase the likelihood of a CPAP trial failure if the combined sleep disorder is not simultaneously addressed. Postgraduate medical education in disciplines other than a dedicated sleep medicine fellowship affords little opportunity to gain proficiency at managing sleep disorders including complicated OSA. Physicians lacking experience in sleep medicine and unaccustomed to the nuances of modern positive pressure devices and interfaces are not likely to provide the longitudinal care mandated by NCD 240.4. This provision of the proposed decision can serve to raise the value of sleep specialists working in AASM accredited
sleep facilities whom, by virtue of specialty training, experience and facility infrastructure, are best equipped to provide chronic care for patients with OSA. The past decade has seen explosive growth in our field. If sleep medicine is to continue its unprecedented growth we need be prepared to develop and embrace disease management paradigms with greater focus on chronic care and less emphasis on facility based testing.

Recognizing the potential for gains in healthcare outcomes and economics afforded by chronic care management paradigms, in January 2007 I proposed a meeting of AASM leadership with aims to enhance our understanding of chronic care models, consider the feasibility of chronic care models in sleep practices and to define the role of the AASM in developing chronic care models specific to sleep medicine. The meeting, scheduled to coincide with the April 2008 meeting of the AASM Board of Directors, fortuitously falls shortly after the final CMS decision on NCD 240.4 allowing AASM leadership to focus the discussion in light of the final ruling. I am optimistic that this conference will serve as a catalyst to promote sleep healthcare strategies that emphasize chronic care of our patients.

This editorial purposely avoids comment on inconsistencies and inaccuracies apparent in the proposed decision by CMS. A number of critical omissions including the failure of CMS to define terms crucial for coverage determination such as “clinical evaluation” and “benefit from CPAP” are similarly excluded as the official AASM response to the proposed modification of NCD 240.4 will elucidate on these and other salient issues. In sharing my experience and perspective it is hoped that this editorial helps prepare the individual sleep specialist and the field of sleep medicine for the challenges ahead.

REFERENCES