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Steve Phurrough, MD, MPA, CPE
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
Mail Stop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244

Re: Administrative File: CAG #00093R2 Continuous
Positive Airway Pressure (CPAP) Therapy for Obstructive
Sleep Apnea (OSA)

Dear Dr. Phurrough:

The American College of Chest Physicians is a professional society of pulmonary, critical care and sleep medicine physicians, cardiothoracic surgeons, cardiologists, and allied health professionals whose goal is to support education and patient-focused care in our areas of expertise, which includes the evolving field of sleep medicine. The ACCP's Sleep NetWork (with 3,000 members) and Sleep Institute are driving forces in sleep medicine, with an interest in fostering excellent patient care and rigorous standards of excellence in the diagnosis and provision of health care to those with sleep disorders. We were grateful for the opportunity to attend the MedCAC on September 12, 2007, and to further comment on the CMS proposed changes for the National Coverage Determination of Continuous Positive Airway Pressure (CPAP).

We agree that unattended home sleep testing (HST) is a medically acceptable means of making a diagnosis of obstructive sleep apnea (OSA) in high-risk adults under certain conditions, and that CMS should provide coverage for CPAP to those patients with a diagnoses made by Type I, II, and III devices, whether tested at home or in a sleep disorders center/laboratory.

We understand the limitations of unattended HST, which include (1) recording a smaller number of signals for later review; (2) technically inadequate recordings because bad sensors or signals that cannot be replaced or corrected during the recording; (3) false-negative study results when patients do not get adequate total sleep time or REM sleep stage and body position effect assessment; (4) low specificity [$< 50\%$] for OSA; and (5) the inability to diagnose sleep disorders other than simple OSA, including complex and central sleep apnea, hypoventilation, and milder forms of sleep-disordered breathing, such as upper airway resistance syndrome (UARS). We feel that HST should be considered a tool to be used in adults in the practice of sleep medicine and guided directly by well-trained physicians, when subjects are at low risk for complicated OSA, based upon history and physical examination. The clinicians interpreting HST data should have training and experience in the interpretation of polysomnography. They should be affiliated with a facility-based sleep laboratory capable of continuing the evaluation and treatment of patients for whom HST does not provide definitive diagnoses and satisfactory clinical outcomes. While we support credentialing of such facilities, we support the concept of more than one accrediting body.

We also agree that a 12-week therapeutic trial period for CPAP would be helpful in excluding patients who might be noncompliant with CPAP use and in need of further evaluation to determine potential future benefit of CPAP. Compliance data alone will not effectively distinguish patients who truly suffer with OSA from those with a false-positive HST, since there may be a placebo effect. Also, many patients with OSA do not get effective subjective relief of symptoms with CPAP alone. There are several matters for discussion during follow-up care that should also be guided by an experienced treating physician or a designated adjunct health-care provider, as future successful CPAP benefit or other treatment might still be expected. Benefit from CPAP use should not simply be judged subjectively but should be objectively assessed by the physician and/or adjunct health-

care providers involved in follow-up care. This may include improvement in symptoms but could also encompass physical signs and other clinical data that the physician judges to be supportive of the continued beneficial use of CPAP. For some (such as those with more than 20 apneas/hour), there is evidence to suggest that there may even be a survival benefit without subjective improvement.

We encourage that CMS demands provision only for CPAP devices (which is virtually the universal case for newer models now anyway) that are equipped with the ability to download the data that physicians will need in order to estimate compliance and aid in the judgment of benefit. This should include the usage time per night, with calendar markings, specific and average usage times, device settings, true pressures, and excessive leaks.

We feel that unattended HST should be reserved, but not required, as the initial assessment for those without serious comorbidities, such as cardiac, pulmonary, or neuromuscular disease. These conditions carry with them the need to more thoroughly evaluate the possibilities of central apnea, hypoventilation, cardiac dysrhythmias, and sustained hypoxemia.

We feel the diagnosis of OSA should be based upon Type I, II, or III devices. Our preferred exclusion of Type IV devices or with clinical evaluation alone as an acceptable means of diagnosing OSA is based on the conclusions of the MedCAC after the meeting of September 12, 2007. With regard to the confidence expressed for the ability to correctly identify patients with OSA and exclude those without OSA, the MedCAC expressed (1) strong moderate to high confidence [score of 4.46] in traditional PSG (Type I); (2) strong moderate confidence [3.77] in Type II HST; moderate confidence [3.31] in Type III HST, but *less than moderate confidence [2.23] in Type IV HST or clinical evaluation alone. In fact, the score for Type IV devices was worse than that of clinical evaluation alone [2.38].*

We would not feel confident in the ability of unattended HST to reliably diagnose OSA in children or to exclude OSA in children, since these tests are much more technically difficult to perform and to interpret, and HST has not been adequately evaluated in this age group.

Patients should be permitted to undergo full sleep laboratory evaluation if HST is not diagnostic and there is an unexplained sleep complaint (eg, excessive sleepiness) or if sleep-disordered breathing is still suspected. Screening tests, such as HST, are appropriate to rule sleep-disordered breathing in but not out.

We support the decision to remove the 2-hour sleep requirement for OSA diagnosis if there is at least the number of apneas or hypopneas documented to satisfy the apnea-hypopnea index required (5 or 15/hour depending on clinical conditions) for a traditional diagnosis.

We also support the decision to remove requirements of moderate to severe OSA and surgery as a likely alternative for the provision of CPAP. Due to the irreversibility, potential for significant harm, and the lack of uniform success of surgical interventions for OSA, HST should not be considered adequate for the diagnosis of OSA as a justification for surgical intervention or for determining its efficacy. Because of the impossibility of a trial period with surgery, Type I (PSG) sleep testing should be done before upper airway surgery should be permitted, and, also, sleep testing should be done after surgery to document benefit and absence of residual disease.

We strongly support the fostering of further clinical research studies that meet the criteria cited by CMS to better identify patients who may benefit from CPAP using optimal evaluation and treatment protocols with presently available and future technologies.

Again, we thank you for this opportunity to respond, and we would be pleased to offer the resources and clinical expertise of the ACCP in any further matters with regard to home sleep studies or the care of patients with sleep-related disorders, in general.

Sincerely

A handwritten signature in black ink, appearing to read 'Alvin V. Thomas', written in a cursive style.

Alvin V. Thomas, MD, FCCP
President