

Comment #60:

Submitter: Edward M. Weaver, MD, MPH

Organization: University of Washington

Date: Fri, May 7, 2004 5:01 PM

Comment:

I strongly support Dr. Davidson's request for CMS coverage for portable multi-channel home sleep testing devices as an alternative to facility-based polysomnography in the evaluation of obstructive sleep apnea.

Home sleep testing offers several advantages:

1. It tests in the patients' natural sleep environment. This important factor is often overlooked but should not be underestimated.
2. It is less cumbersome to patients. Fewer testing leads translate into less distraction in bed and more natural sleep.
3. Improved access to diagnosis and treatment, which ultimately reduces medical costs.
4. Less cost per patient.
5. It is adequate in 80-90% of patients who are thought to have sleep apnea.

Sleep physicians have demonstrated the cost-effectiveness of home sleep testing at Group Health Cooperative in western Washington [1]. Group Health Cooperative is a large health maintenance organization that realized in the mid 1990's that it was not adequately managing sleep apnea in its >500,000 members. They realized that they could not succeed by simply trying to expand the in-facility polysomnography laboratory, because the number of tests required and the cost of the tests were both increasing exponentially.

Instead, they used a home sleep testing program (just like the proposal for which Dr. Davidson requests coverage) to increase access and reduce costs. They developed a program using a multi-channel home sleep test (cardiopulmonary test without electroencephalogram, electrooculography, electromyography, etc.), and they measured outcomes and costs.

After two years, they had impressive results. They completed 698 portable tests. Only 8% required repeat testing due to lack of diagnosis or a technical problem. Standard facility-based polysomnography was needed in just 11% of all patients. Overall testing rates increased 129%. The average cost per case of suspected sleep apnea decreased by 36%. The per-member, per-month health plan cost decreased by 13.5%. No deaths, hospitalizations, or Emergency Department visits occurred while undergoing portable testing or home CPAP titration.

A great proportion of sleep apnea patients remain undiagnosed, which translates into worse health outcomes and increased costs. Analysis of 147,000 Veterans Affairs patients with a diagnosis of sleep apnea revealed a 27% increased mortality risk for untreated compared to treated patients, after adjusting for age, race, gender, comorbidity, and year of diagnosis [2]. Sleep physicians at Group Health Cooperative showed that undiagnosed sleep apnea is associated with healthcare costs significantly higher (almost double) than age/gender-matched controls from the same population [3].

I anticipate that you will receive significant vociferous opposition to Dr. Davidson's proposal, especially among many sleep physicians that benefit financially from facility-based polysomnography. I ask you to consider their major, inherent conflict of interest and weigh their comments accordingly. I recognize that this conflict of interest exists even in some very prominent, highly respected sleep physicians.

As a final note, I wish to convey my background to provide a context for my support of Dr. Davidson's proposal. I am a clinical epidemiologist studying sleep apnea. I am also an Otolaryngologist-Head & Neck Surgeon who specializes in sleep apnea care as the Surgical Program Director of the Sleep Disorders Center at the University of Washington. I participate on several national committees: Chair of the Sleep Disorders Committee and Chair-elect of the Outcomes Research Subcommittee of the American Academy of Otolaryngology-Head & Neck Surgery; member of the Research Committee of the American Academy of Sleep Medicine; and member-elect of the Research Committee of the Sleep Research Society. My own sleep apnea research is funded by NIH and by the American Geriatrics Society.

References:

1. Lewis DA. Home monitors for the diagnosis of sleep apnea: The Puget Sound experience, American College of Chest Physicians: Chest 2000, Chicago, 2000.
2. Weaver EM, Maynard C, Yuch B. Mortality of veterans with sleep apnea: Untreated versus treated. Sleep 2004:(abstract)(in press).
3. Kapur V, Blough DK, Sandblom RE, et al. The medical cost of undiagnosed sleep apnea. Sleep 1999; 22:749-55.

Comment #61:

Submitter: Dominic A. Munafo, M.D.

Organization: Sleep Data, Inc.

Date: Tue, May 4, 2004 4:34 PM

Comment:

I am writing to express my strong support for Dr. Davidson's proposal that CMS cover type 3 monitors for the diagnosis of obstructive sleep apnea syndrome.

During the last seventeen years I have had an opportunity to see the practice of sleep medicine from a number of perspectives. Among these were sleep research associate, pulmonary fellow, university faculty, private practice, and medical director of a sleep diagnostic company.

While working as Pulmonary & Critical Care faculty at the University of California, San Diego, in the early 1990's I oversaw the care of many patients with severe sleep apnea. Unfortunately, we had little to offer them. There were no clinical sleep labs at either the University Hospital or the VA Medical Center then or now for that matter. Typically, we would have to use a piece of loaned diagnostic equipment from a manufacturer's representative, to do an ambulatory study. Once a diagnosis was made, we had no ability to manually titrate CPAP pressures in a lab. The result at the VA was that patients were sent home with a CPAP device, a pressure manometer, and a screwdriver! They were begun on an empiric amount of CPAP and instructed on the technique of adjusting the pressure based on symptoms, snoring and their bed partner's reports. Out of this necessity sprang the essentials of the program that is currently in place at both the University Hospital and the VA. The results have been remarkable. Instead of thousands of patients waiting months for a referral to a sleep lab, patients were efficiently diagnosed and begun on therapy. Fortunately, we now have access to ample numbers of portable recorders and CPAP devices. However, the principle remains unchanged. We found that patients were well served and that only a small fraction required referral to a sleep lab. Now we can use auto-titrating CPAP devices as well as symptom-based adjustments of CPAP pressures. In addition, with portable recorders we have the luxury of doing follow-up studies on the patients with severe disease so as to be assured that they are being adequately treated. Surely, this is a more appropriate use of precious clinical resources.

Amazingly, the University is just now committing the resources for a TWO bed clinical laboratory that may open this year. This is drop in the bucket if we are to insist that all patients undergo full polysomnography (PSG).

Fortunately, the medical literature is increasingly supportive of the ambulatory model. The article last year by Fitzpatrick et al., (1) confirmed results previously published by Coppola (2). Patients can be educated to assist in the titration of their own CPAP pressures. Once again, monies previously being spent on full PSG can be much better spent on the education and follow-up of patients with sleep apnea. Time and time again it has been shown that without aggressive education and follow-up, patient compliance with CPAP is poor. Why spend all of the resources on the diagnosis and leave nothing for the all-important aspects of therapy and patient education?

I would like to comment briefly on some of the literature that is often cited to criticize portable testing. The fundamental point often made is that portable testing fails to render an apnea-hypopnea index (AHI) equivalent to "the gold standard AHI" derived from PSG. Unfortunately, what is barely mentioned is that "the gold standard AHI" is not a single standard but actually varies considerably from lab to lab. Laboratory derived AHIs are, in fact, derived of many different combinations of methods and definitions (3,4,5). The literature clearly shows that an AHI determined in one sleep laboratory may have little if anything in common with an AHI determined in another laboratory using an alternate definition for hypopnea and/or a different method for detecting respiratory events. In fact, ranges between AHIs of at least ten-fold have been reported (4,5). If one cannot standardize the "gold standard" how can you possibly compare another technology to it and arrive at a scientific conclusion?

I fully realize that continuing work needs to be done to determine how best to implement portable diagnostic techniques in various patient populations and in different healthcare delivery systems. However, those of us with considerable experience have seen that far more good comes from improved access to care than from the ridiculous pursuit of an illusory diagnostic certitude.

I would also respectfully submit that no analysis of a diagnostic paradigm is complete without a careful consideration of the context in which it is placed. What of the cost in morbidity and mortality for the millions of patients who will remain undiagnosed and untreated in the absence of a more aggressive and integrated approach to sleep apnea? Young's seminal article demonstrated that over 80% of the patients with sleep apnea remain undiagnosed (6). Every day, hundreds of patients with undiagnosed severe sleep apnea have major surgery. Many will receive respiratory depressants and be placed at considerable risk (7). Countless Americans are on our roads with severe daytime sleepiness due to undiagnosed sleep apnea. There is not a single piece of evidence to support the contention that limiting sleep apnea testing to sleep laboratories ultimately benefits patients or the public health. In fact, I feel quite strongly that the public health is being harmed enormously by the limitation of care that results from the current guidelines.

From a strictly financial perspective, the increased access to health care will no doubt increase the amount paid out for diagnosis and therapy. However, several analyses suggest that it is less expensive to treat sleep apnea than to manage all of its myriad complications (8). Large payers such as Blue Cross/Blue Shield, Cigna, CCN and HealthNet cover portable testing. Of course, from an ethical standpoint, financial factors should not be the primary driving force behind public policy anyway.

While I acknowledge a financial interest in the use of ambulatory testing, I urge you to remember that those who have lobbied so hard to maintain the status quo have enormous financial, career and research interests at stake as well. The rapidly growing number of PSG labs is testament to their financial viability as cost centers for hospitals. Unfortunately, this is not the best use of our healthcare dollar.

In the California health care system it is quite common to rely on portable diagnostics. Sleep Data, Inc. presently services major health care systems including Sharp Healthcare, Mercy Healthcare, Scripps Healthcare and elements of the Veteran's Affairs system. In addition, Kaiser Permanente, the University of California San Diego, and the San Diego Veteran's Affairs Medical Center all rely predominantly on portable studies, as does the Group Health System in Washington State. This says nothing of the fact that many other countries of the world rely in part or totally on portable diagnostic paradigms.

In summary, there can be little doubt that some form of portable testing will be the ultimate end point. The only issues are when and which techniques will prove best. The recent article by Flemons points out the fact that even with herculean efforts to increase the number of sleep labs and formal sleep physicians we will fall woefully short of the capacity necessary to adequately serve our patients (9). Dr. Pack's accompanying eloquent editorial distills the matter to its essentials, "Access is the issue." (10) We must proceed proactively to help insure that the overwhelming need of our patients is met in a timely and cost-effective fashion. To do less should not be an option.

Thank you in advance for your gracious attention and any consideration you may give this request. I would be delighted to meet with you at your convenience to further discuss the program we have found to be so successful.

References:

1. Fitzpatrick MF, Alloway CE, Wakeford TM, MacLean AW, Munt PW, Day AG. Can patients with obstructive sleep apnea titrate their own continuous positive airway pressure? *Am J Respir Crit Care Med* 2003;167(5):716-22.
2. Coppola M, Lawee M. Management of obstructive sleep apnea in the home: the role of portable polysomnography. *Chest* 1993;104:19-25.
3. Moser NJ, Phillips BA, Berry DT, Harbison L. What is hypopnea, anyway? *Chest* 1994 Feb;105(2):426-8.
4. Redline S, et al. Effects of varying approaches for identifying respiratory disturbances on sleep apnea assessment. *Am J Respir Crit Care Med* 2000 Feb;161(2 Pt 1):369-74.
5. Tang JP, et al. Identification of sleep-disordered breathing in children: variation with event definition. *Sleep* 2002 Feb 1;25(1):72-9.
6. Young T, Evans L, Finn L, Palta M. Estimation of the clinically diagnosed proportion of sleep apnea syndrome in middle-aged men and women. *Sleep* 1997;20:705-706.
7. Lofsky A. Sleep Apnea and Narcotic Postoperative Pain Medication: A morbidity and mortality risk. National Patient Safety Foundation 2002.
8. AASM Position Statement. Cost justification for diagnosis and treatment of obstructive sleep apnea. *Sleep* 2000;8:1-2.
9. Flemons WW, Douglas NJ, Kuna ST, Rodenstein DO, Wheatley J. Access to diagnosis and treatment of patients with suspected sleep apnea. *Am J Respir Crit Care Med* 2004;169(6):668-72.
10. Pack A. Sleep-disordered breathing: access is the issue. *Am J Respir Crit Care Med*. 2004 Mar 15;169(6):666-7.